FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Wednesday, May 1, 2002

1:30 p.m.

TRIAL VOLUME 38

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

KAREN G. BOKAT, Attorney
PHILIP M. EISENSTAT, Attorney
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2912

ON BEHALF OF SCHERING-PLOUGH CORPORATION:

JOHN W. NIELDS, Attorney
LAURA S. SHORES, Attorney
Howrey, Simon, Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(202) 783-0800

ON BEHALF OF UPSHER-SMITH LABORATORIES:

J. MARK GIDLEY, Attorney
CHRISTOPHER M. CURRAN, Attorney
White & Case, LLP
601 Thirteenth Street, N.W.
Suite 600 South
Washington, D.C. 20005-3805
(202) 626-3610

P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Docket 9297, we're on the record. I'm here for closing and final arguments.

Before we get started, I have a housekeeping matter. I remind the parties that I need copies of exhibits that are cited in your post-trial briefs, one copy. The parties should confer so that I don't have, for example, three copies of an exhibit just because all three of you cited it.

Any questions on that?

MR. NIELDS: No, Your Honor.

MR. CURRAN: No, Your Honor.

MS. BOKAT: No, Your Honor.

JUDGE CHAPPELL: Are we ready?

MS. BOKAT: Yes, Your Honor.

JUDGE CHAPPELL: Who will be arguing for complaint counsel?

MS. BOKAT: I will, Your Honor, Karen Bokat.

JUDGE CHAPPELL: You may proceed. Go ahead.

MS. BOKAT: Thank you.

Good afternoon, Your Honor.

JUDGE CHAPPELL: Good afternoon.

MS. BOKAT: Schering-Plough Corporation entered into illegal agreements with its competitors

Upsher-Smith and American Home Products to pay them money in exchange for them delaying their generic competition. Each day of delay in generic competition harmed consumers because it forced them to continue to pay the higher branded price because they had no generic available.

We can see how much higher that price was if we look at what happened once Upsher-Smith was permitted to bring its generic to market. Upsher priced its product at almost half off the price of Schering's K-Dur 20. So, until Schering permitted Upsher to come to market, consumers were paying almost twice as much for K-Dur 20 as they would have paid if a generic had been available to them.

This case is so simple. Those two facts alone, an agreement among competitors not to compete and harm to consumers, constitute a violation of Section 5 of the Federal Trade Commission Act. We ask Your Honor to issue an injunctive order against Schering and Upsher-Smith so they will not repeat this conduct in the future and cause future harm to consumers.

In early 1997, Schering had a monopoly of 20 milliequivalent potassium chloride tablets. Sales of Schering's K-Dur 20, its 20 milliequivalent tablet, were over $153 million in 1996, the last full year

before the agreement with Upsher-Smith. Those are the revenues that Schering sought to protect with these agreements.

Upsher and AHP had developed generic versions of Schering's K-Dur 20 that would compete directly with that product. Once either Upsher's or AHP's generic came to market, it would take sales away from Schering and eat into Schering's revenues.

We can see the effect the generic competition would have on Schering if we look at what actually happened. This is a graph that we have seen before. It measures in total prescriptions with the red line sales of K-Dur 20 and the blue line sales of all generics. So, we see that K-Dur 20 sales on the red line were continuing along nicely until September 2001 when the agreement finally permitted Upsher to bring its generic to market. Then K-Dur 20 sales plummeted, and the sales of all the generics took off.

K-Dur 20 stood to lose $7 million a month in sales, whereas Upsher's sales would amount to only about $1 million a month. So, that difference gave Schering the wherewithal to pay Upsher to stay off the market.

On June 17th, 1997, Schering and Upsher entered into a settlement agreement. Under the terms of that

agreement, Schering had committed to pay Upsher $60 million, and Upsher committed that they would not bring their generic to market until September 1st, 2001. A little later, Schering entered into a second agreement with American Home Products, which I'll refer to today as AHP. Schering promised to pay AHP up to $15 million depending on how soon AHP's generic received tentative approval from the Food and Drug Administration.

In other words, the sooner AHP got approval and got that much closer to being an actual competitor, the more money they would get from Schering, up to $15 million. AHP committed to hold their generic off the market until January 2004.

Through these two agreements, Schering was able to maintain its position as the only marketer of a 20 milliequivalent tablet and to protect its revenues. Both of these agreements are anti-competitive and illegal because they harmed consumers, delayed generic competition and kept prices of the 20 milliequivalent tablet higher than they would have been.

The contemporaneous documents and the testimony of both respondents' officials and other witnesses prove that these agreements are illegal whether you look at them under a per se or a rule of reason analysis. The agreements, plus Schering's monopoly,

constitute monopolization by Schering. The agreements, plus evidence of the parties' specific intent and evidence of acts in furtherance of conspiracies, establish that Schering and Upsher and Schering and AHP conspired to monopolize.

I want to deal with four major themes this afternoon. The first is Schering paid Upsher and AHP for delay. The second is the $60 million that Schering paid Upsher was not all for the Niacor license. Third, Schering had market power. And fourth, complaint counsel do not have to prove the underlying patent litigation in order to make out an antitrust violation.

Starting with the first, no one disputes that Schering actually paid Upsher and AHP. The central question in this case is whether those payments were for delay. Respondents contend that the payment to Upsher wasn't for delay but for the Niacor license. They contend that payment to AHP was because the judge forced them to settle. The evidence in the record, however, proves that the payments were for delay.

Upsher and AHP made persistent requests for payment and wouldn't settle the patent litigation without payment. Schering granted Upsher and AHP's request for payment. Schering's concern was just what those payments would look like, because Schering knew

that competitors couldn't pay one another not to compete. No matter who looks at the payment, whether it's the Federal Trade Commission, the Department of Justice, the State Attorney General or the consumer who needs potassium chloride, such a payment looks offensive.

Schering had an incentive to pay for delay; that way, it could protect its revenue stream. Upsher and AHP had an incentive to accept Schering's payment and to delay their generic competition because that gave them a certain amount of money, and they didn't even have to take on the risks of competing.

The $60 million payment to Upsher was not for the Niacor license. We know this because this was an extraordinary payment for a less than ordinary product. Also, Schering's due diligence on the Niacor product was strikingly superficial. Third, Schering and Upsher's conduct post-agreement isn't consistent with Schering really being interested in marketing the Niacor product.

Fourth, Schering turned down a license on a superior niacin product about the time it supposedly paid $60 million for the Niacor license. And last, if we look at the response of the marketplace to this license, over 40 companies were offered the very

license by Upsher, and not one of them offered any money for it.

Schering had market power. We know Schering had market power because complaint counsel proved actual anti-competitive effects. The parties knew that Schering would have market power until the 20 milliequivalent generic came on the market. We can see that from the parties' own forecasts. The actual sales experience of K-Dur 20 before and after September 1st, 2001, also show that Schering had monopoly power up until that date of generic entry. The generic 20 milliequivalent tablets had a unique impact on Schering's sales of K-Dur 20 that none of the preexisting potassium chloride supplements had been able to have.

And last, we as complaint counsel do not have to prove the patent case, and the Court doesn't have to decide the underlying patent case. The outcome of the patent litigation with both Upsher and AHP was uncertain. Schering paid to eliminate that uncertainty, and under the antitrust laws, competitors can't agree not to compete, whether the competition is certain or uncertain. Established case law tells us that complaint counsel don't have to prove the patent case.

Let's focus first on the payments for delay, starting with the agreement between Schering and Upsher. The terms of the agreement itself and the evidence of the negotiations leading up to the agreement prove that the payments were for delay. Indeed, Schering's counsel, John Hoffman, conceded that the payment to Upsher was at least in part for delay.

He was asked at trial:

"QUESTION: And the paragraphs referred to for which consideration is being paid include paragraphs that explicitly talk about settlement of the lawsuit and the entry date, do they not?

"ANSWER: That's correct."

Now, let's look at the language of the agreement between Schering and Upsher itself, focusing on paragraphs 11 and 3. Paragraph 11 provides, "In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, SP Licensee," Schering, "shall make the following payments to Upsher-Smith." Then it lists three payments, $28 million, $20 million and $12 million, adding up to $60 million.

Paragraph 11 explicitly states that the $60 million in payments was for paragraphs 1 through 10, which includes paragraph 3. There we find Upsher's

commitment to keep its generic off the market. Paragraph 3 provides:

"Upsher-Smith agrees that it will not market in the United States its Klor Con M20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001."

Now, this is interesting. The Klor Con M20 is the generic of Upsher on which Schering had sued Upsher for patent infringement. So, Upsher is committing here to hold that generic off the market and also any other sustained release microencapsulated potassium chloride tablet even if it doesn't infringe Schering's patents.

Ian Troup tried to run away from the explicit language of this agreement. He said the $60 million payments were just for the licenses from Upsher back to Schering, but those licenses are contained in paragraphs 7 through 10, and 11 clearly says that the payment is in exchange for 1 through 10, which includes 3, with a commitment to hold the generic off the market.

The very language of the agreement impeaches Mr. Troup. His testimony on this point is simply not credible. He is encouraging the Court to misread the agreement, which he has to do, because this agreement

by itself, if you just read the face, means that respondents lose.

Now, if we look at the negotiations that led Upsher and Schering to this agreement, the documents and testimony about the negotiations also show that Schering entered into this agreement to obtain Upsher's delays and protect Schering's monopoly profits. The contemporaneous Schering documents show us what Schering's concerns were and their strategy for dealing with them.

Let's look first at the March 1995 memorandum. This was written within Key Pharmaceuticals, which is the Schering subsidiary responsible for K-Dur and K-Dur 20. It was written March 8th, 1995. The subject is, "K-Dur Long Term Strategy." One of the issues signaled in this memorandum is generic competition to K-Dur 20 may come within two years. So, given that this memorandum was written in 1995, Schering is anticipating it may confront generic competition as early as 1997.

What were Schering's objectives for dealing with this issue? Well, one of them was maximize the length of time to introduction. What was Schering's strategy for dealing with the issue? Well, that was redacted. Schering asserted attorney-client privilege

for that portion of the memorandum, which is perfectly appropriate, but Schering also at trial put on witnesses who said Schering told Upsher that Schering's counsel advised Schering they couldn't pay for delay.

They seem to be asking there for two inferences, that Schering's counsel actually gave them that advice and that the client, Schering, followed the advice. They may not, however, use attorney-client privilege as both a sword and a shield. When complaint counsel tried to ask about that legal advice, through either seeking documents, asking questions in depositions or asking questions at trial, Schering asserted their attorney-client privilege. So, they can't now ask for inferences on this topic having denied us that information.

Luckily, the redacted portion of this document is filled in for us by Schering's executive summary. Schering devised a strategy to settle the patent litigation with Upsher in a way that would delay generic entry. Schering already recognized that an agreement with Upsher might cause antitrust concerns. They wanted any agreement to pass FTC muster.

Schering realized that they would have to pay Upsher-Smith in order to secure such a deal. The language of the executive summary reads, "Additionally,

any deal with Upsher-Smith should be lucrative and provide them with a guaranteed revenue stream of approximately $25-20 Million per year until another K-Dur ANDA is approved." So, what Schering is saying is that to get any deal with Upsher, they're going to have to guarantee them a revenue stream, but Schering will pay that only until some independent third party comes on the market with a generic. After that, there's no incentive for Schering to keep paying Upsher-Smith, because Schering would be looking at generic competition anyway.

Schering calculated what this guaranteed revenue stream would have to be. They assumed for the purpose of this calculation that Upsher's generic would come on the market in 1998, and they projected the revenues through the year 2001 and figured that the net present value, discounting for time, was $45 to $55 million.

Schering knew they couldn't blatantly pay Upsher not to compete, so they were looking for a device to get Upsher this revenue stream in a way that wouldn't look quite so bad. One option they considered was review UPS portfolio and purchase pipeline products or in-line portfolio for SGP to promote.

This executive summary foreshadows exactly what

Schering decided to do. They paid Upsher-Smith $60 million over two years, which had a net present value of about $54 million, close to the top of that range, and they attached to it a license of Upsher products back to Schering so that it wouldn't look so bad.

John Hoffman described these negotiations between Schering and Upsher-Smith during his investigational hearing. He was asked:

"QUESTION: Was there a reason for the negotiations of the license and the patent settlement occurring at the same time?

"ANSWER: I believe I described Mr. Troup's statements to that, that it was all well and good for us -- for Schering to propose a license to take effect in the future. But that they needed to work out some way to get some cash for their own needs, and that maybe they would license something to us."

Between May 21st and June 17th, Schering and Upsher negotiated and concluded their agreement. The primary negotiators were Ian Troup, president of Upsher-Smith, Martin Driscoll, vice president of sales and marketing for Key, the Schering division responsible for K-Dur, and Raman Kapur, head of Schering's generic unit.

Schering's counsel told you in opening

statement that he would call witness who participated in the negotiations with Upsher. He listed John Hoffman, Martin Driscoll, Jeff Wasserstein and Raman Kapur. Mr. Kapur's testimony would have been enlightening, because he was one of the main negotiators for Schering, and he attended more meetings with Upsher than any other Schering official. He attended four out of the five meetings. If called to testify at trial, Mr. Kapur would have testified about the May 28th meeting.

Ian Troup was looking for a revenue stream to replace his generic of K-Dur 20. That's based on Mr. Kapur's investigational hearing. He would also --

MR. CURRAN: Your Honor, I object to any use of the investigational hearings during closing if it's addressing the case against Upsher-Smith.

MS. BOKAT: We're addressing cases against both Schering and Upsher-Smith. At a minimum, complaint counsel should be able to use this testimony against Schering-Plough.

JUDGE CHAPPELL: No need to object, Mr. Curran. This is not evidence. This is merely argument.

MR. CURRAN: Very good. Thank you, Your Honor.

MS. BOKAT: Mr. Kapur also would have testified that Ian Troup wanted to bring his generic to market

immediately.

Mr. Wasserstein's testimony might have been helpful, because he attended the June 16th meeting, the very last meeting between the parties, at which they finally struck the agreement. Mr. Wasserstein would have testified that Mr. Troup said he needed a stream of income to replace the money he would have made with Klor Con M20. That's based on Mr. Wasserstein's investigational hearing.

Mr. Driscoll was the only Schering representative at the first meeting with Upsher-Smith, and he, together with Mr. Kapur, were the only Schering representatives at the second and third meetings. If Mr. Driscoll had testified about the initial May 21st meeting, he would have said the two sides were discussing when Schering would permit Upsher's generic to enter as a way to settle the patent litigation. Mr. Troup told Mr. Driscoll that if Upsher delayed entry, it would need money to replace lost revenue. That's based on Mr. Driscoll's investigational hearing.

He also would have testified, Ian Troup asked for $60 to $70 million based on percentage of the dollar sales that Schering would have lost to generic competition.

Neither Mr. Driscoll, Mr. Kapur or Mr.

Wasserstein testified at trial about the negotiations with Upsher. John Hoffman, Schering's in-house counsel, is the only one called who attended any of those meetings, but he attended only the fourth and fifth. So, we have no testimony from Schering witnesses about the May 21st, May 28th or June 3rd meetings, and no Schering business person who participated in the negotiations testified at trial. Their absence shows how afraid Schering is of the facts.

Let's look at what the evidence in the record does show about this series of five negotiation meetings. The two parties discussed possible concepts for settling the patent litigation, including the concept of allowing Upsher to come into the market before patent expiration. We have that from Mr. Driscoll's investigational hearing.

Mr. Troup wanted his generic on the market within one year. There was considerable negotiation back and forth about this entry date, and finally Mr. Driscoll said Schering wouldn't allow Upsher on the market before September 2001. Mr. Troup's position was that Schering had to pay Upsher to settle this patent case. Mr. Driscoll gave an answer in his investigational hearing:

"ANSWER: Mr. Troup's position was that, in his mind, the only settlement was for us to pay them to settle the situation."

Ian Troup was looking for a revenue stream to replace his generic of K-Dur 20, which was testified to by Mr. Kapur as well, and this is in his investigational hearing. He was asked:

"QUESTION: Right. I was trying to go back to the first meeting you attended in Minneapolis. At that time, is Mr. Troup looking for a revenue treatment replacement for his generic version of K-Dur 20?

"ANSWER: I really didn't focus on the discussions, but that was my impression, that he was looking for a revenue stream."

Mr. Troup actually testified at trial that in the first meeting he told Mr. Driscoll that if his generic didn't come to market until a date closer to patent expiration, Upsher would lose revenue, and he asked Mr. Driscoll what Upsher was going to do about money.

Jeffrey Wasserstein also remembers Mr. Troup saying that he needed a stream of income to replace the money he would have made with his generic. According to Mr. Wasserstein, that may have been at that final June 16th meeting, or it may have been in subsequent

telephone calls.

Ian Troup specified he wanted $60 to $70 million to stay off the market. He said this at the May 21st meeting. Mr. Driscoll testified in his investigational hearing when he was asked:

"QUESTION: Did Mr. Troup indicate how much money he wanted to receive from Schering-Plough for the settlement?

"ANSWER: I recall. I recall in the course of our discussions, and I believe it was at that first meeting, I believe it was at that first meeting, that he was using in the neighborhood of -- he wanted a payment in the neighborhood of 60 to $70 million from Schering to Upsher-Smith to end the litigation."

Upsher-Smith had run some models on the impact of Upsher's entry on Schering's sales. Mr. Driscoll testified when he was asked:

"QUESTION: Did Mr. Troup say anything about where he got his figures?

"ANSWER: I recall that he had discussed that they had run some models indicating the impact, if you will, of their product on the market upon our K-Dur 20 milliequivalent, and that served as the basis for what they felt he should receive as a payment for the litigation to end."

Ian Troup threatened that if Upsher launched its generic, other companies would introduce generics as well. Ian Troup said in his hearing or the question was:

"QUESTION: What did you say to Mr. Driscoll?

"ANSWER: I said we're going to win this case, and we're going to come on to the market, and if we --" this is Upsher " -- come on to the market, it could open up a flood gate of products.

"QUESTION: When you say open the flood gates, what do you mean by that?

"ANSWER: If we got on to the market and other people would have come on to the market at different times.

"QUESTION: Other people would come on the market with a generic version of K-Dur 20?

"ANSWER: Yes."

Now, that's interesting, because at the time of these negotiations, it wasn't certain whether Upsher-Smith would actually have that 180-day exclusivity and block other generics. This passage from Mr. Troup suggests he thought they would, but even if they didn't, what is certain is that once Upsher's generic was on the market, there would be no flood gate, and at most, 180 days later, other generics would

be permitted to come to market.

On June 16th, 1997, the parties held their last negotiation meeting. They discussed the settlement of the lawsuit and entry date for Upsher and a license of Niacor. By the end of the meeting, the terms -- all the major terms of the agreement had been reached. Schering would pay Upsher $60 million; Upsher would delay entry of their generic; and the delay would be until September 2001.

On June 17th, the parties signed a binding agreement subject only to the approval by Schering's board, and Schering sent the agreement -- excuse me, took to the board the idea of this agreement to get their approval, and they sent a memorandum to Schering's board. In the memorandum, we see on a subsequent page, under Payment Terms, the language, "In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from sales of Klor Con had they been successful in their suit." Then it lists those guaranteed payments, $28 million, $20 million and $12 million.

So, the discussion of the $60 million is linked

to payments to make up for Upsher's lost income. There's no reference in here to a Niacor license at all. When the Schering board considered this agreement, we know from this language that they knew that Schering was providing money to Upsher to replace what Upsher would have earned from their generic and that that payment had been a condition of the deal.

Schering got what it wanted. It actually paid the $60 million to Upsher-Smith, and Upsher held their generic off the market until September 1st, 2001, but Upsher wasn't the only threat to Schering's monopoly position. There was also AHP. Whether or not Upsher had that 180-day exclusivity, AHP was a threat to Schering, because if Upsher didn't have the exclusivity, as soon as AHP won their patent litigation, they could come to market. If Upsher did have the exclusivity and AHP won the patent litigation, that AHP victory would trigger Upsher's 180 days, and six months later, AHP and other generics would be permitted to come to market. So, that threat gave Schering an incentive to pay AHP, but AHP wasn't as big a threat as Upsher. They weren't as close to FDA approval, so AHP got less money than Upsher did.

The judge in the patent suit between Schering and AHP had indicated he had some significant questions

about the strength of Schering's position, and he also noted that in his view Schering's case was not a slam-dunk. Now, while the possibility of AHP winning that patent suit may not have been huge, the potential damage to Schering's revenues from an AHP victory was tremendous. So, Schering paid AHP to remove that threat.

It's no surprise that Schering and AHP began discussing settlement of their litigation. Initially, AHP offered Schering a fairly typical settlement agreement. If Schering would license its patent to AHP, AHP would pay a royalty fee, but Schering turned them down. Schering counteroffered that if AHP abandoned its generic, Schering would permit AHP to co-promote Schering's K-Dur 20. AHP declined that offer because they had antitrust concerns about this co-promotion proposal, but AHP was willing to forebear from competing with its generic if it was paid by Schering.

We see that from a letter that was written by AHP's outside counsel to Schering's outside counsel. It refers here to ESI Lederle, which is a subsidiary of AHP, the entity that Schering had actually sued. Here, AHP says, "However, we are agreeable to discussing an arrangement where Key would make an appropriate payment

to ESI Lederle, and ESI Lederle would receive a license to enter the market at some subsequent time (for example, in 2002) and forebear from entering the market until then."

Mr. Kapur described these negotiations between Schering and AHP. He was asked:

"QUESTION: Was ESI offering to stay off the market with their generic version of K-Dur if the case settled and they were paid?

"ANSWER: For a certain period of time if the case settled and they were paid so they could make up their revenue stream."

The negotiations between Schering and AHP focused on the concept of compensating AHP for the revenues they would lose by not competing. During an August 1997 settlement conference, Schering's counsel, Charles Rule, expressed the view that a payment to AHP to make up for their lost revenues would be more defensible than a payment based on the revenues Schering stood to lose. Mr. Rule's statement shows that Schering was not refusing to consider payment to AHP, and his approach is the one that the parties adopted.

Shortly after that settlement conference, AHP provided Schering with estimates of what it would lose

by staying off the market. That settlement agreement that Martin Driscoll negotiated on a Friday night late in January 1998 was just an agreement to settle the patent litigation. As Mr. Driscoll testified, the settlement agreement had nothing to do with licenses from AHP to Schering. The terms of that agreement were that Schering would pay AHP up to $15 million depending on how quickly AHP got tentative approval for their generic, and AHP agreed to hold their generic off the market until January 1st, 2004. Then the judge dismissed the patent litigation.

Over the next several months, however, there was continued negotiation between Schering and AHP as they tried to reduce their agreement to writing, there were drafts going back and forth, and they added provisions that restrained AHP's generic competition. AHP added the commitment that they would market only one generic between January 2004 and 2006 when the Schering patent expired, that AHP would not file a second ANDA for a generic of K-Dur 20, and that AHP wouldn't help any other company with a bioequivalence study to K-Dur 20.

At the time they added these restrictive provisions, the case was no longer before the judge, so they can't say the judge pressed them into adopting

those restrictive provisions. AHP got approval from the FDA quickly enough that they got the full $15 million from Schering, and to date, they haven't sold their generic. This is a naked payment for delay unobscured by any pretextural license.

Upsher and AHP, at the time of these agreements, were the only two companies who had filed for generics to K-Dur 20, so that these two agreements ensured there would be no generic competition until at least September 2001, and indeed, there was no generic competition until that date. Until then, consumers had to keep paying the brand price for K-Dur 20, because there was no generic available to them.

Dean Goldberg from United Healthcare, a large managed care organization, came and testified at trial here, and he explained the benefits of generics to consumers. He testified as follows.

"Generics really represent one of the most powerful ways that we can help manage pharmacy costs, and so we want to do whatever we possibly can to promote the use of generics, not only because it costs us less, but because it costs our members less who pay less out of pocket when somebody dispenses a generic product."

With these two agreements, Schering managed to

protect their profit margins on K-Dur. Their margins were about 80 percent, so of every $100 in K-Dur sales, after paying the costs of manufacture, sales and distribution, Schering still had $80 to take to the bank. Now, that doesn't account for the previous R&D on K-Dur or for R&D on the other Schering products that turned out to be dry holes, but that is cash that Schering would have from these sales as long as they didn't have generic competition.

We've done up some new pie charts to try and illustrate what this amounted to. We're showing here the difference between or the amount of Schering monopoly profits and how much they were able to retain through these agreements. We used here the time period December 1998 through June of 2001, which is conservative, but we used as a starting point the fact that the FDA gave final approval to Upsher's generic in November of 1998. So, at that time they were free to go to market but for the agreement. So, rather than try to parse part of November, we simply started with December. Then we used for this a document we have from Schering's files that's their quarterly accounting reports, and we have those only through June of 2001. So, while Schering protected their K-Dur profits until the end of August, we stopped with June 2001.

Now, that profit document we were using was all of K-Dur, the 20 and the 10, whereas K-Dur 20 sales are about 90 percent of total K-Dur, so we multiplied by 90 percent the total from this Schering report for the entire time period, but we recognized that even with generic competition, the brand doesn't lose all of its sales. It retains some, and we're just trying to measure the difference in revenues with and without generic competition. So, we assumed for the purposes of these pies that K-Dur 20, even with generic competition, would keep half its sales.

Now, we know from actual data that they didn't keep half, but we were being conservative. We figured that the difference in profits, with and without competition for the time period, was $248 million. So, that's the excess that consumers had to pay while they continued to have no generic available to them and had to purchase K-Dur 20. Now, Schering, of course, passed some of those revenues on to Upsher, $60 million, and AHP, $15 million, but nonetheless, Schering still had $173 million more.

Now I'm going to shift over to the Niacor license. We've been talking about K-Dur so far, the potassium chloride. Now we're going to shift to a niacin that's used to treat cholesterol.

Schering asserted that it told Upsher-Smith Schering couldn't pay for delay but could pay for a separate deal; however, the deal would have to stand on its own two feet. So, Schering has set the yardstick for measuring this license. Did it stand on its own two feet? The problem for Schering is, they didn't bother to find out if that license was worth $60 million before they agreed to pay that amount. Schering didn't know if the deal would stand on its own two feet. Schering didn't care, because the $60 million was really for Upsher's commitment to hold its generic off the market, not for the Niacor license.

We know that from five different factors that I'll list briefly and then go into in a little more detail. First, the $60 million noncontingent payment is the largest in Schering's history for a product that was less than ordinary. Second, Schering didn't do its normal due diligence. Its due diligence on Niacor-SR was strikingly superficial. Third, Schering and Upsher's lack of coordination in the period after the agreement demonstrates no interest in actually marketing this licensed product.

Fourth, just prior to entering into the Niacor license, Schering turned down a license on a better sustained release niacin. And fifth, Upsher had

offered this very same license to over 40 companies, and not one of them offered one dollar in noncontingent payments for it.

I'll concentrate first on the $60 million noncontingent payment. As I mentioned, even today, it's the largest in Schering's history. Dr. Levy examined 33 other Schering deals, including the four that Schering's counsel told Commissioner Anthony were the most analogous to the Niacor license. More than half of them had noncontingent payments less than $5 million, and the largest up-front payment was $30 million, half of what Schering supposedly paid for Niacor.

Niacor is at best an ordinary product, because it's a sustained release niacin, and those products have known side effect problems. Also, Niacor was going to have to compete with the statins that were already sold in the licensing territories. Mr. Audibert, who did the commercial assessment of Niacor, estimated its sales at $45 to $150 million a year, and his boss, Mr. Lauda, said that a $100 million product is not a huge product.

Moreover, Schering didn't build into the structure of this license any protections for itself. We know that developing pharmaceutical products is

inherently risky. They can fail for a variety of reasons, including not getting regulatory approval, having manufacturing problems, maybe the marketplace won't accept them. Schering and other pharmaceutical manufacturers know about this risk, so normally they would structure licensing payments with less of the total amount in noncontingent payments and more of it depending on something happening.

It might be in royalties that are calculated based on actual sales or it might be milestone payments triggered by something happening, like regulatory approval, and that way, the licensee protects itself against the risks that the product will never come to market, because they only have to make the payment once these stages are reached.

Schering agreed to be obligated to pay the full $60 million no matter what happened with Niacor, and let's look at what did happen. Schering made the initial $28 million payment. Then Upsher stopped developing Niacor-SR. Nonetheless, Schering went ahead and made the $20 million payment. Then Upsher informed Schering that it was not pursuing Niacor, and nonetheless, Schering made the last payment of $12 million, because Schering was getting what it wanted, Upsher's commitment not to enter the market. So, it

didn't matter what happened to Niacor.

Second, Schering didn't perform anything like what would be normal due diligence for Schering and for other pharmaceutical companies. Dr. Levy testified that Schering's due diligence was strikingly superficial on Niacor. All Schering did was a commercial assessment.

Now, we learned what Schering was trying to do with that commercial assessment. Upsher and Schering had been negotiating about Upsher delaying its generic entry. Upsher was insisting on $60 to $70 million for delay, and Schering was concerned about the appearances of the payment and wanted a deal to justify the payment.

Mr. Lauda gave James Audibert the assignment to do this commercial assessment. He described -- this is Mr. Lauda now -- described the assignment this way. He was asked:

"QUESTION: Do you recall when you first heard that Schering-Plough was considering taking a license to market the Niacor-SR product?

"ANSWER: I don't recall an exact date. I do recall a conversation from Ray Kapur who informed me that they had an opportunity to license several projects -- several products from Upsher, that the

principal one was a European or international opportunity for Niacor and could I perform an assessment of that against a background that the value would probably -- the payment would probably be about $60 million.

"QUESTION: So Mr. Kapur told you the payment would be around $60 million?

"ANSWER: He told me that was the expected range, yes."

So, instead of trying to figure out what this Niacor license was worth, Schering was trying to determine whether the license would justify the $60 million payment that Ian Troup was insisting on. Normally, Schering had a multidisciplinary team of dozens of people over several months looking at a prospective license.

This table shows the contrast between the due diligence on Niacor in the first column, where we see they did only the financial review and the commercial assessment, versus several other Schering deals where they performed all the elements of due diligence.

Schering claims that James Audibert was uniquely qualified to analyze Niacor, but the evidence does not support that claim. Mr. Audibert doesn't have the technical or legal experience to analyze patent

issues. At the time he was doing this analysis, he hadn't worked in regulatory affairs for over 20 years, and he had no experience with pharmacokinetic studies for niacin, although the FDA was insisting that Upsher successfully complete a PK study if they wanted the sustained release claim.

Mr. Audibert testified that when working on assessments for other licensing projects, he frequently consults people outside his department for guidance on regulatory, clinical and toxicology issues, but he didn't consult with any such people on Niacor. Mr. Audibert didn't have the expertise to be doing this due diligence all by himself.

Now, respondents claim that due diligence wasn't necessary because Niacor was a very straightforward product. Niacor was not straightforward. It was a sustained release niacin, and sustained release niacins had known liver toxicity problems. Schering itself was well aware of those problems.

Just two months before licensing Niacor, Schering had commissioned a survey of ten medical experts. This was in conjunction with looking at Kos' Niaspan. Based on their experience with cholesterol-lowering drugs, these experts reported to

Schering their concerns about the safety and efficacy of sustained release niacins. Given those concerns, Niacor should have had a review by clinical experts and clinical data, but Schering didn't bother with that study.

Also, the marketing of sustained release niacin in Europe was not a straightforward proposition. The other companies to whom Upsher had offered this Niacor license, many of them in rejecting the license voiced concerns about side effects and about the limited market potential. Let's look at just a couple of those letters.

The first is from Knoll. They say, "Regretfully, we have to inform you that our experts, after internal evaluation in the respective departments and our US subsidiary, decided not to pursue this offer any further. The small market for the product is one of the reasons for this decision."

The second letter is from Solvay that says, "We had a look at the market and we have come to the conclusion not to proceed further. The statins group of products are actually widely prescribed and there is not much room anymore for the nicotinic acids," which include Niacor.

The post-agreement conduct of these two parties

and their lack of coordination shows that Schering wasn't really interested in marketing Niacor-SR. Upsher made the decision in December of '97 or January of '98 to stop development on Niacor. We can see that from an internal Upsher document, their January 1998 monthly update on Niacor, which says, "Project has been put on hold. Only minimal activity will continue." But Upsher didn't even notify Schering that it had stopped work on this product for which Schering had paid $60 million supposedly until October of 1998, eight or nine months later, as we see from this letter dated October 6th, 1998 from Upsher's chief financial officer to Ray Kapur. It says:

"I am writing to confirm that Upsher-Smith Laboratories, Inc. has suspended all research on Niacor-SR."

If Schering was seriously interested in marketing Niacor-SR, why did Upsher wait eight months to tell them they had stopped work on it?

Schering turned down a license on a superior product about the same time it entered into this Niacor license. Schering had been looking at Kos' sustained release Niaspan. Kos' product was closer than Upsher's to FDA approval. It had a better side effect profile, and Kos' product needed to be taken only once a day at

bedtime rather than twice a day with meals like Niacor, which is important on this product because niacins have a side effect of flushing, which is unpleasant for patients, and the thought was if the patient could take it once a day at bedtime, a lot of the flushing would occur overnight, and then it was less problematic, whereas Niacor had to be taken twice a day, so some of the flushing presumably would happen during the day.

Schering did make a written offer to Kos for a co-promotion on this product, but it had no noncontingent payments in it, not one dollar, and in mid-June, Schering discontinued the negotiations.

The reaction of the marketplace to an offer of Niacor-SR also tells us that the $60 million wasn't for Niacor. Upsher offered a license on Niacor-SR to over 40 companies. Upsher contacted virtually everybody who was a pharmaceutical manufacturer or distributor outside the United States, primarily in Europe. That's according to the trial testimony of Upsher's expert Dr. Kerr. The majority of those over 40 companies either never responded at all or turned down the offer without stating a reason.

Some of the them, however, when they wrote back to turn down the offer did state a reason. Side effects or the lack of sales potential. Only five

companies even met with Upsher-Smith, and none of them offered any money for the license.

Respondents contend that complaint counsel say the license was a sham, but that is incorrect. We don't say it's a sham. We say instead the $60 million was not for this license. If the only payments were the ones we see in the agreement for milestones and royalties, we wouldn't be here this afternoon. We would be out enjoying a beautiful spring afternoon. But we are here because Schering paid $60 million in noncontingent payments without attempting to see if the deal stood on its own two feet.

To defend the agreement with AHP, Schering says that the magistrate and the judge in the underlying patent litigation were aware of the terms and sanctioned them, but there is no evidence in this record that the judge or the magistrate ever saw the written agreement that the parties reached in June '98, five months after the court had dismissed the patent litigation.

There's also no evidence that the judge ever was made aware of the terms of the agreement in principal that the parties reached in January. Even if the magistrate was aware of those terms of the agreement, they were never incorporated into an order

of the court, so they don't constitute an antitrust defense, and respondents have offered no citation for the proposition that we should look at these agreements under rule of reason rather than per se because of some judicial scrutiny.

Martin Driscoll tried to excuse the agreement by saying the magistrate threatened if the two parties didn't settle that Friday night, Mr. Driscoll was going to have to be in the courthouse on Saturday. Now, while we can sympathize with somebody wanting to spend their Saturday other than driving to the courthouse, that is not an excuse for a competitor paying another competitor to delay and not to compete.

Schering offered testimony from Anthony Herman that the judge was refusing to hear the case and pressed the parties to settle, but experienced lawyers like Schering's know that judges often press parties hard to settle, yet if the parties can't reach a settlement, the judge hears the case, and in fact, the transcript of the proceedings between Schering and AHP has a reference to the judge talking about going to trial.

Upsher tries to justify its agreement with Schering by saying the agreement allowed Upsher to come to market before patent expiration, but this

justification defies common sense. Schering didn't pay $60 million to let Upsher come to market earlier. At the time of the agreement, Schering had two options. They could litigate or they could settle. If Schering thought that by litigating they would get an entry date of September 2001, it wouldn't make any sense to pay Upsher $60 million. If Schering thought that they could settle without a payment and get Upsher to agree to hold off until September 2001, it again wouldn't make any sense for Schering to pay the $60 million. That payment makes sense only if it got Schering a later generic entry date than it could have gotten either by litigating or by settling without a payment.

Now I turn to the point of Schering's monopoly. The facts I've been discussing this afternoon show that Schering had an intent to delay generic entry, that Schering was willing to purchase delay and Schering divided its monopoly profits with Upsher and AHP to purchase that delay. Those facts in the record comport with economic theory.

You'll recall perhaps these three pie charts, because they've been with us since opening statement, and they were used by some of the witnesses. These are abstract illustrations of the monopoly, competition and retained monopoly situations that explain the incumbent

monopolist's incentive to pay for delay. The red pie in the middle represents the incumbent brand company's margins in the monopoly situation.

The second pie represents the competitive situation, and here we see that the incumbent still has margins, but they're not nearly as large as they were in the monopoly situation. The generic entrants have profits, because they're making revenues here, and some of that is profit to them. The remainder, due to the fact that the generic is cheaper than the brand, is savings to consumers.

The third represents the situation where the monopolist pays the entrant not to compete. Here, all the sales initially go to the brand company, but some of those revenues are paid to the entrants to purchase their delay. So, not all of the money stays with the brand company, but they have a lot more than they would in the competitive situation.

Indeed, respondents' experts Dr. Kerr and Dr. Addanki testified that branded pharmaceutical products stand to lose more dollar sales than the generic will gain by going to market, so the monopolist earns more without competition than the monopolist and the entrant can earn together in the competitive situation, which provides both the incentive and the means to pay

generics to stay off the market.

Schering had market power. That's the power to control prices or exclude competition. The basic points on this are that complaint counsel have proved the anti-competitive effects, which is sufficient to make out market power. Second, the parties' forecasts show that they anticipated K-Dur would have market power until a 20 milliequivalent generic came on the market. The actual sales experience of K-Dur 20 showed that it had market power until September 2001. And the 20 milliequivalent generic tablet had an impact on K-Dur 20's sales that the preexisting potassium chloride supplements had never had.

First, complaint counsel has proved the anti-competitive effects. Schering's agreements kept generic competition off the market until 2001. In the meantime, Schering was able to charge its supra-competitive prices and yet expand its sales.

The three companies knew that Schering had market power. If we look first at a Schering market research backgrounder, it says, "Although generic entry is not likely until 1998 the impact of a generic 20 mEq product would be significant." And then if we look at two Schering forecasts, these -- this is actually an illustration we made derived from two forecasts, one

Schering did before the Upsher agreement and the second one after. We see what Schering anticipated by way of the difference in K-Dur sales with and without generic competition.

The blue line represents the forecast that was done June 5th, 1997, which is before the Upsher agreement. There, Schering was anticipating that its K-Dur sales would increase until 1998 and then with generic competition would drop off sharply. The second forecast represented by the red line was done after the Upsher agreement in November 1997. By that time, Schering knew they wouldn't have generic competition from Upsher until 2001, so you see the forecast of K-Dur sales was continuing to increase through the year 2000.

Schering knew that with the Upsher agreement in place and the threat of generic competition pushed off into the future, K-Dur's sales would be protected. This is illustrated by a K-Dur marketing plan. This was written August 1st, 1997, just a few weeks after the Upsher agreement was reached. It says, "With a new lease on life, K-Dur 20 sales will be," I assume that's reignited, "via the coordinated field force efforts of Key Specialty and Innovex." We can feel Schering breathe a sigh of relief for K-Dur 20.

If we look at the actual experience with K-Dur, we see that from the mid-nineties to the end of the nineties, Schering was increasing K-Dur's price each year. This actually breaks down K-Dur into three different package sizes, but you see that each year from '95 through 2000, Schering was taking at least one and in some years two price increases. At the same time, Schering's margins on K-Dur were increasing each year. This bar chart has net sales.

Now, this I should say is for all of K-Dur, but remember, K-Dur 20 is 90 percent of that anyway. So, their net sales represented by the gray bars are increasing each year, and their product margins represented by the red bars are also increasing each year. So, these price increases can't be explained just by increasing costs, because the margins are increasing at the same time.

Now, K-Dur 20's sales measured in prescriptions shows an increase, too. It's not just dollar sales. This shows actually just K-Dur 20. From January 1997 through July 2001, you see that its sales begin in 1997 at about 800,000 prescriptions, and then they grow to over 900,000 by July of 2001.

K-Dur's price was not constrained by the existence of other potassium chloride supplements.

I'm sorry, Your Honor, did you want me to wait?

JUDGE CHAPPELL: Go ahead. We're dealing with some minor technical problems.

MS. BOKAT: Just minor?

JUDGE CHAPPELL: You have my hundred percent attention.

MS. BOKAT: Okay, thank you.

JUDGE CHAPPELL: And if I happen to miss anything, I look at CaseView to catch up.

You may proceed.

MS. BOKAT: Thank you.

The prices of 8 and 10 milliequivalent tablets were eroding, because there were generics of the 8 and 10s on the market. At the same time, because K-Dur 20 had no generic, their prices were continuing to increase. There's a nice quote from Denise Dolan on this. She was Upsher's product manager for Klor Con. She said, "Generics have begun to play a major role in the 8 and 10 mEq arenas -- resulting in downward pricing pressure."

Schering successfully priced K-Dur 20 at almost double the price of the generic 20 mEq tablet as long as it faced no direct generic competition, so Schering had the power to control price, but when Upsher's generic finally entered, as permitted by Schering, in

September 2001, that market power ended, which we can see from our little tried and true abstract that we've seen before. Schering's market power petered out beginning in September 2001. It lost sales, and the generic's sales took off.

Respondents would have us prove the underlying patent case, but it is not necessary to prove the outcome of the patent case to establish that a horizontal agreement is an unreasonable restraint of trade. While the outcome of the two patent cases was uncertain and whether Upsher or AHP's generic would be permitted to come to market before patent expiration is also uncertain, the antitrust laws condemn payments to eliminate even uncertain competition, just as they condemn payments to eliminate certain competition, because consumers would have been better off even with the uncertain possibility of Upsher and AHP coming to market earlier than they were with the certain entry date chosen by these parties.

Upsher and AHP's generics were a threat to Schering, and Schering paid to eliminate that threat. Those were payments to eliminate uncertain competition which are illegal under the antitrust laws. No case law suggests that the prosecution must prove the patent outcome to make out an antitrust case. In Masonite,

the patent holder had sued or threatened to sue its competitors for patent infringement. To resolve those disputes, Masonite licensed its patent to these would-be competitors but said they had to charge a price for the product set by Masonite.

In its decision, the Supreme Court assumed that the patent was both valid and infringed but found that the licensing agreements went beyond Masonite's legitimate rights and constituted illegal price fixing.

In Singer, the Supreme Court didn't resolve the patent suit but still held that a patent settlement agreement violated the antitrust laws. There, the lower courts and the Patent Office had made no finding that the patents were invalid or not infringed. The Supreme Court didn't even reach the issue of whether the patents were invalid. As the Supreme Court stated in its opinion, "The possession of a valid patent or patents does not give a patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."

There are also more recent decisions from two district courts in the Cardizem and Terazosin cases. Those were antitrust cases arising out of agreements by the brand name company to pay the generic to stay off the market. Those were partial patent settlements.

Both those district courts rejected arguments that the patent law or the antitrust law required those plaintiffs to establish the likely outcome of the underlying patent case.

The law as laid out by the courts is in the right place. Plaintiffs in an antitrust case don't have to prove who would have won the patent case, because it's illegal to eliminate competition, whether that competition is uncertain or certain.

Upsher contends that its generic couldn't have entered the market any earlier than September 2001 even absent the agreement with Schering, but the evidence in the record contradicts that contention. Upsher represented to the federal district judge in the patent case in a motion filed before its agreement with Schering that the only thing keeping Upsher's generic from the market was the 30-month stay on FDA approval.

A mere week after receiving tentative approval from the FDA, Upsher filed an emergency motion with the Federal Court seeking an injunction to lift the 30-month stay on FDA's final approval of Upsher's generic. The motion stated that the stay was the only thing keeping Upsher from marketing its generic product. That is a judicial admission that Upsher was ready to launch, and anything Upsher says now to the

contrary is less than the truth.

In fact, in 1997, Upsher projected its entry either in the fall of '97 or early 1998. This is an Upsher document talking about various launch dates. The earliest is August 1st, 1997, the middle one October 1st, 1997, the latest possibility, January 1st, 1998.

Then there's a second Upsher document, this dated April 10th, 1997, with a target market introduction for their Klor Con M20 between September and November 1997.

In the first half of 1997, Upsher had a team working on marketing-related tasks in preparation for the launch. We know that from Mr. Kralovec's investigational hearing. He was asked:

"QUESTION: Did you have any sense in the first half of 1997 of where Mr. Dritsas," and we'll remember that he was head of marketing for Upsher, "Mr. Dritsas and his group were with the advertising effort?

"ANSWER: Again, I knew that we were trying to coordinate the entire launch and we had a launch team that was working on all of the activities."

Upsher had at that time the facilities it needed to manufacture the product. Mr. Kralovec, again in his investigational hearing, was asked:

"QUESTION: You mentioned that Upsher-Smith would have to have some additional equipment in house for the launch of the 20 mEq product.

"ANSWER: Right.

"QUESTION: What equipment was that?

"ANSWER: Well, the most important we wanted to -- the most important piece of equipment that we needed was the tablet press, a new tablet press.

"QUESTION: When did Upsher-Smith anticipate they would have that in place?

"ANSWER: We would have -- it would have been put in place about in the fall of '97. We had tablet presses. I don't want to imply that we didn't have tablet presses. We had the capability of manufacturing this product, but we wanted to expand our capabilities, so it wasn't like we couldn't manufacture it, but this would have helped us enhance our capabilities."

IPC was going to perform an intermediate manufacturing step for Upsher's generic. In 1997, it had the facilities needed to produce the batch size that the FDA had approved. We know that from the trial testimony of Mr. Gould. Upsher had, in fact, scheduled production of validation batches at IPC for June and had reserved IPC's facilities in August of 1997 to begin commercial scale production.

The proof of the benefit to the parties and the harm to consumers caused by these agreements is the evidence of what's happened since September 1st. Upsher's product finally came on the market priced at approximately 45 to 50 percent below K-Dur 20. In the first month, generics gained 20 percent of the prescriptions for 20 mEq tablets. By the second month, generics had 50 percent of the prescriptions. And in just the third month, the generics had 60 percent of the prescriptions. So, by the third month, the majority of consumers were paying half the price for 20 mEq tablets that they had to pay for K-Dur 20 before September 1.

Before that entry date, consumers who suffer high blood pressure and often life-threatening heart problems were footing the bill for an arrangement that let Schering continue to charge supra-competitive prices and these three companies to pocket the profits.

In opening statement, Upsher's counsel described Upsher as the consumer's best friend, fighting vigorously for generic entry. Upsher did fight for generic entry until June 17th, 1997, when Schering offered them $60 million to stay off the market. Then Upsher lowered the priority of the generic project and shifted personnel to other

projects. Upsher didn't do further planning for the marketing and manufacturing because it had the $60 million in its pocket and knew it couldn't launch until 2001.

The evidence we have discussed proves every element of the Commission's complaint. The complaint charges that Schering's agreements with Upsher and AHP unreasonably restrained trade, that Schering had a monopoly and engaged in conduct to preserve that monopoly and that Schering and Upsher and Schering and AHP conspired to monopolize, acted with specific intent and engaged in overt acts in furtherance of those conspiracies.

In order to decide that these respondents have violated Section 5 of the Federal Trade Commission Act, the Court must determine that at least part of the payments was for delay. Closely related to that, that at least some of the $60 million was not for the Niacor license. And then last, for the monopolization and conspiracy to monopolize counts, did Schering have market power.

Let's look for a minute at the count about agreements to restrain trade. There are two analytical frameworks that the courts and the Commission apply to agreements to determine if they unreasonably restrain

trade. The first is per se, and the second is rule of reason. But we don't need to tie ourselves in knots over which of these analytical frameworks is the most appropriate for the facts of this case, because complaint counsel has introduced sufficient evidence to prove the case under either analytical framework, per se or rule of reason.

Per se, if an agreement is of the type that would always or almost always tend to restrict competition and decrease output, it is deemed per se unreasonable, and the Court need look no further. Paying a competitor not to enter is so inherently anti-competitive that it has long been held to be a per se violation. The courts have sufficient experience with paying a competitor not to enter the market that such an agreement can be held per se illegal even if the prior agreements arose in industries not before the Court.

The Cardizem and Terazosin courts, again, they had before them antitrust cases where the brand name company had paid the generic to stay off the market as a partial settlement of patent litigation. Those two district courts found those agreements to be per se illegal.

Now, the rule of reason, if there is a

plausible and valid justification for the restraint or if the anti-competitive nature of the restraint is not sufficiently clear, then the courts typically look at the restraint in the circumstances of the affected market, but the proffered justification must be that the restraint is actually pro-competitive, and the burden is on the respondents or defendants to prove a valid and plausible justification.

Now, the Cardizem court faced the exact same justification we have here. Those parties said that their agreement was pro-competitive because it included a license that let the generic come on the market before patent expiration. The court rejected that justification.

Respondents here have also offered justifications from their expert witnesses, but they fail as well because they're contrary to established theory in the fields of those respective witnesses. The experts didn't determine if their models applied to the facts here, and the economic models predict that the settlement agreements will be anti-competitive rather than pro-competitive.

For the purpose of the rule of reason analysis, complaint counsel have proven the anti-competitive effects. Schering intended to keep generic products

off the market and succeeded in doing that. As a result of the agreements, there was no generic competition until September 2001. Until then, Schering made all the sales of the 20 mEq tablets at its supra-competitive price.

Having proved actual effects, we don't have to prove market power, because market power is a proxy for -- that is used if you're trying to determine the likely effects, if you don't have evidence of the actual effects. We have proven actual effects, but we nonetheless have also proved market power. Schering's agreements are illegal under either a per se or rule of reason approach.

Respondents would have complaint counsel prove the but-for world, that competition actually would have occurred absent these agreements, but they're wrong. Even under a rule of reason, we have to prove only the likely effects at the time of the agreement.

The California Dental Association case teaches that these per se/rule of reason labels don't mean much. The fundamental question is whether we can do enough analysis to determine the nature of the agreement and to predict its likely effect. Complaint counsel have answered California Dental's question. We've presented enough evidence to permit the Court to

determine the nature of these agreements. They're agreements to pay a competitor not to compete. We have shown the actual effects. The agreements allowed Schering to continue charging supra-competitive prices.

Now, the monopolization count. Monopolization requires not only market or monopoly power but also action to preserve the monopoly. As we discussed earlier, Schering had market power. Schering's action to preserve it was the negotiation of the agreements to keep generics off the market.

The conspiracy to monopolize count. The agreements themselves constitute conspiracies. The specific intent is shown by evidence that Schering was planning to try to delay generic competition. The proof of Upsher and AHP's specific intent is that they demanded payment, a split of the monopoly profits, if they were to delay their competition. The overt acts were execution of the agreements, Schering's making the payments, the generic companies accepting the payments, and the generics holding their products off the market.

By entering into the agreements, Schering protected its monopoly revenues and reaped millions of dollars of profits, some of which it gladly shared with Upsher and AHP. Schering, Upsher and AHP were the winners; the consumers who had to keep paying

supra-competitive brand price were the losers.

We ask that Your Honor conclude as a matter of law that Schering's agreements unreasonably restrained trade, that Schering monopolized and that Schering and Upsher and Schering and AHP conspired to monopolize the relevant markets all in violation of Section 5 of the Federal Trade Commission Act.

This case should send a signal to other companies that agreements among competitors will not -- agreements to avoid competition will not be tolerated. Agreements between brand manufacturers and generic manufacturers that delay generic competition pervert the very purpose of the Hatch-Waxman Act, and they have the potential to run up pharmaceutical costs by billions of dollars.

To avoid the possibility that these two parties will engage in such conduct in the future, we ask that the Court issue the order that is attached to our post-trial brief.

Thank you very much for your attention.

JUDGE CHAPPELL: Thank you.

Who's first?

MR. NIELDS: I believe I am, Your Honor.

JUDGE CHAPPELL: Let's go.

MR. NIELDS: May I have just a moment to set

up?

JUDGE CHAPPELL: Yes.

(Pause in the proceedings.)

JUDGE CHAPPELL: Whenever you're ready.

MR. NIELDS: Thank you, Your Honor.

JUDGE CHAPPELL: It's times like this I need a gavel. Go ahead.

MR. NIELDS: Good afternoon, Your Honor. This is somewhat later in the spring than we had originally anticipated being together, and the parties have I know filed perhaps more paper than was necessary in the Court's lap. I will try my very best to be as pointed as I possibly can during this summation, Your Honor.

JUDGE CHAPPELL: Thank you.

MR. NIELDS: Your Honor, complaint counsel have written in one of their briefs, and I've put it up on the -- whatever we call this thing, I used to call it ELMO, but the Power Point, and this is the statement they made:

"The pivotal factual dispute in this case is whether Schering's $60 million non-contingent payment to Upsher-Smith was for the Niacor-SR license, or instead for the delayed September 1, 2001 entry date."

We would agree with that, Your Honor, at least to this extent, that if Schering paid and received fair

value on the Niacor license transaction, all parties have agreed that there's no violation of the antitrust laws in the Upsher settlement, and it is the Upsher settlement I will be addressing first.

Complaint counsel wrote, Your Honor, in their trial brief, "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or the payment of fair market value in connection with 'side deals' to such an agreement."

Professor Bresnahan, Your Honor, their expert, said this: "If Schering-Plough had made a stand-alone determination that it was getting as much in return from these products as it was paying, then I would infer that they were not paying for delay."

Schering's expert, Dr. Willig, said exactly the same thing. He's asked:

"QUESTION: Why did you conclude that a settlement with a patent split that has a side deal without net consideration," and he had already explained that what that meant is if Schering got fair value for its $60 million, that would be without net consideration, "poses little or no harm of social welfare?

"ANSWER: Well, like splits of patents to

settle patent litigation that have no side deals at all, there are real social benefits to the settlement of the patent dispute in and of themselves. The fact that there is a side deal that's linked, given that the side deal has no net consideration entailed in it, means that the side deal raises no additional risks of harm to competition."

All of the parties are in agreement, Your Honor, that if the Niacor license transaction was a fair value transaction, $60 million for the rights to Niacor and the other products, if that was a fair value transaction, there's no violation of the antitrust laws.

Complaint counsel, Your Honor, have the burden on this issue, to prove that it was not a fair value deal and that it was instead payment for delay. I don't think there's any dispute about it, but here it is in the Commission rules, "Counsel representing the Commission...shall have the burden of proof," and we would submit, Your Honor, that they have not met their burden.

They tried at the beginning to meet their burden through the testimony of Professor Bresnahan. I'm not sure Ms. Bokat mentioned him at all, but they relied very heavily upon him in their proof. He

started off, Your Honor, purporting to find evidence of payment for delay in the testimony that had been given by the people who negotiated the Schering-Upsher settlement. He purported to find evidence of payment for delay or agreement to pay for delay in that testimony, but in fact, it wasn't there.

He gave the following testimony on cross examination:

"QUESTION: Professor, I am going to start off by asking you some questions about your opinion that Schering, in fact, paid Upsher for delay. On direct, you said that that opinion was supported by deposition testimony by participants in the negotiation. Do you recall that?

"ANSWER: I do.

"QUESTION: And in fact, in your report, you have a separate section headed Direct Evidence in which you conclude that there is direct evidence that Schering purchased delay from Upsher, and then you proceed to discuss the deposition testimony of the participants in the negotiation. Do you recall that?

"ANSWER: I do.

"QUESTION: And the testimony you discuss is testimony from Mr. Hoffman, Mr. Driscoll, Mr. Troup and Mr. Kapur. Do you recall that?

"ANSWER: I think that's right, yes.

"QUESTION: Isn't it true, Professor, that each one of these people testified that Schering refused to pay Upsher to stay off the market?

"ANSWER: Yes, that's right."

And Your Honor, there was abundant testimony to that effect. We have quoted a lot of it in our brief. I would mention that Mr. Kapur, Mr. Driscoll and Mr. Wasserstein, whom Ms. Bokat referred to earlier as not having testified live, testified both in investigational hearings and in depositions, and their testimony is in the record. Complaint counsel has had absolute, complete and full opportunity twice to ask them all the questions that they wanted. And all of them testified that -- and they testified repeatedly -- that Schering, every time the notion of payment for delay was raised in negotiations, and it wasn't often, the Schering people said no, flat no, will not do it.

What the testimony about the negotiations actually shows, Your Honor, is this, and I should say that not surprisingly, not all of the testimony is exactly the same in details. We have a lot of people, a lot of time had elapsed, and there are differences, minor differences, but in substance, the following is what that testimony shows.

After Schering indicated it would not pay for delay under any circumstances, the parties started discussing a way of settling the case that involved compromising on an entry date, splitting the patent life and agreeing on an entry date sometime before patent expiration. The parties were trending toward a September 1, 2001 date, an entry date, as a way of settling the case, and at some point Mr. Troup said to Mr. Hoffman, when Mr. Hoffman said, look, we've already agreed on a September 1, 2001 date, he said, well, that's all fine for you, but we have cash needs, the concept being that even if that's a fair settlement date, 2001, September 2001, even if that's just the right and fairest compromise of the litigation, Upsher would then give up any chance at all of getting any cash flow from this product for the next four years, and that was a problem for Upsher.

Schering said they would consider entering into another transaction that might generate some cash for Upsher so long as it stood on its own two feet, so long as it was a transaction that Schering would do anyway on its own merit. At that point, Upsher offered Niacor and then eventually some other less important products to license to Schering for sale overseas. Schering asked the global marketing department of Schering,

under the direction of Tom Lauda, to evaluate the Niacor license opportunity and tell them whether it was worth $60 million.

Mr. Lauda and Mr. Audibert were the Schering people who did that evaluation. They did it without knowing about the patent litigation. Mr. Audibert did his evaluation, and I'm going to come back to his evaluation in much greater length in a few moments, but for now, he did his evaluation, he made sales forecasts, and the sales forecasts that he came up with show that within three years of launch, which would be he projected in 1999 or two years later there would be launch, three years -- third year after launch, the sales would reach over $100 million. Mr. Lauda concluded that an opportunity for a product like that was worth much more than $60 million to Schering.

The Schering negotiators then agreed to pay $60 million, some other terms to the agreement. A contract was negotiated, settlement, license to Niacor rights combined, and then that contract was made contingent upon the approval by Schering's board of directors. A memorandum went to Schering's board of directors which told the board exactly how the negotiations had gone, told the board that the Niacor license opportunity had arisen during settlement discussions, told the board

that Upsher had cash needs which they needed to meet before they would be willing to settle, and it told the board that any license transaction in which Schering paid cash to Upsher-Smith had to stand on its own merit.

I know the Court has seen this before, but this is our last chance, and so I'm going to put this once again on the ELMO, I hope. Above, Your Honor, is the place where the board is informed that this arose in the context of a settlement, that Upsher indicated they needed to deal with their cash needs, and then the board is told, "we informed them that any such deal should stand on its own merit independent of the settlement."

There's a redaction there, Your Honor, for attorney-client privilege. Complaint counsel have repeatedly throughout the course of this trial, I'm sure you'll recall Mr. Orlans doing this, tried to cast dispersions on Schering's claiming of the attorney-client privilege there. It even made up language that might be there that had nothing to do with the attorney-client privilege. That's improper. No inference can be drawn from Schering properly asserting its right to consult in private with its counsel.

Now, the board of directors members gave testimony about what they understood that means, namely what I just showed Your Honor. This testimony, Your Honor, was brought out by complaint counsel during the deposition of Schering board member Patricia Russo, who was then I think CEO of Eastman-Kodak.

"QUESTION: What does it mean where it says, 'Any such deal should stand on its own merit independent of the settlement?'

"ANSWER: What it means to me is that the licensing agreement that was being proposed would have to stand on its own merits.

"QUESTION: Does that mean it would have to be an agreement that Schering would enter into if there were no patent settlement?

"ANSWER: Yeah, it would be an agreement that would make sense in and of itself independent of anything else."

Hans Becherer, Your Honor, was a former executive at I believe John Deere, is asked:

"QUESTION: What does it mean that any such deal should stand on its own merit independent of the settlement?

"ANSWER: My recollection of the board meeting where this was presented and discussed, it was made

very clear to the directors that we were looking at this license agreement which had to stand on the merits of the license agreement."

Your Honor, the board of directors then ratified the agreement and it became a contract, and they ratified it based on their understanding and belief that the Niacor license transaction stood on its own merit, that Schering was getting fair value in return for its $60 million in the form of the rights to market Niacor overseas.

The board, Your Honor, also had in front of it by that time, at the back of the memorandum that they had given to them in connection with that board approval, they had in front of them some calculations which Schering's finance department had made from Mr. Audibert's sales projections, and those calculations showed that the Niacor license had a net present value, you'll recall, an economic value of from $225 to $265 million.

Now, Your Honor, that is what the evidence shows about how this agreement was negotiated and how it was ratified and approved by the board of directors. There is no conflicting evidence in the record. Two things are shown, Your Honor, by the proof about the negotiations and approval. One is that the Niacor

license and the settlement are connected to each other, no question about that. Mr. Hoffman testified to that and it is very clear from the board minutes and from the board memorandum. They're connected to each other in just the way I described.

Two, the second thing it shows is that Schering-Plough did the Niacor license deal, paid the $60 million, because it stood on its own merit, because in their judgment they were receiving equal or more in value than they were paying.

I asked Professor Bresnahan about these two things together, namely, that the license and the settlement were connected and that the Niacor license was done for fair value. I'd like to show you the testimony he gave. This I believe was at the very, very end of his cross examination. I think this may be the end of his cross examination.

"QUESTION: Professor, isn't this like negotiations 101?

"ANSWER: I don't know what you mean.

"QUESTION: Wouldn't any good mediator say, that's a very smart way of solving this problem? This is a very good way for the parties to try to come up with a settlement that makes sense? They pick a date that is fair, Upsher has a problem with settling on

those terms because they want cash a lot now, and they're giving up the opportunity of getting it under a settlement, so the parties do a fair market value transaction that is a good deal for both parties and solves Upsher's desire for cash... what's wrong with that?

"ANSWER: Under the assumption that it's a fair market value for both parties and under the assumption which I -- which I don't know how to deal with that you defined fair ignoring the high rated discount, the -- you know, if it's a -- if it's a --" and then he says, "if they stop at a fair market value transaction, generally I don't think there's a problem."

Your Honor, just to take it one step further, Schering had an expert, I'm sure you recall him, Dr. Zola Horovitz, he's a licensing expert with a huge amount of experience in licensing generally with a science background as well and some knowledge of cholesterol, and he was asked this question:

"QUESTION: Dr. Horovitz, do you have an opinion, having reviewed all the information that you've relied upon in forming your opinions, as to whether or not the deal for Niacor-SR did stand on its own two feet?

"ANSWER: Yes, I believe I said that a number

of times, that the economics of that deal based on their protections and knowledge -- projections and knowledge at that time would make the Niacor-SR deal a good one for Schering and would stand on its own two feet."

Now, complaint counsel has argued that the use of the word "consideration" in paragraph 11 of the actual agreement means that the Niacor deal did not stand on its own two feet and that the $60 million was actually paid for a delayed entry date. Well, Your Honor, first of all, the language of the contract doesn't lead to that conclusion at all. In fact, the language of the contract refers to the $60 million as a royalty payment, and royalty is a term that means payment for license rights received, and the only license rights Schering received were to Niacor and the other four products.

The interpretation that complaint counsel wants to give the word "consideration" in paragraph 11 of the contract conflicts with all of the evidence in this case. We might as well not have had a trial. It conflicts with all of the testimony, including the memorandum sent to the board of directors before they approved this contract and their testimony as to their understanding.

Your Honor, the next thing that Professor Bresnahan tried to point to in support of his opinion that Schering was paying for delay rather than paying for Niacor was something he called a revealed preference test, and it had to do with Kos and the negotiations that Schering had with Kos over Niaspan. I don't understand why they went into this, Your Honor. I believe that the negotiations with Kos are extremely helpful to Schering.

First of all, Schering's interest in Kos' Niaspan product confirms that Schering had a keen interest in sustained release niacins wholly independent of any settlement, because there was no settlement in the wind with Kos, and there was testimony, Your Honor, and documentary evidence that Schering's interest in the sustained release niacin product of Kos had a lot to do with the fact that Schering had a cholesterol-reducing drug in its pipeline and very much wanted to get out in the field selling a product in the cholesterol-reducing field before its product hit the marketplace.

Second, Your Honor, Schering's negotiations with Kos taught it a lot about sustained release niacins. Most important, they taught Mr. Audibert that one sustained release niacin product was about to get

approved by the FDA, because he asked a Kos person on a telephone call and found out that Niaspan had already passed medical review, which meant that it was going to get approved.

Third, Schering did sales projections for Niaspan, sales in the United States. I've put them up on the board, Your Honor. These were done by Ray Russo, who testified here in court, and his projections for Niaspan in the United States are very much in line with Mr. Audibert's projections for Niacor overseas. Mr. Russo's numbers are a little bit bigger, but not much. They start sooner because Kos was going to hit the market sooner, but they are very close.

That matters, Your Honor, because no one, complaint counsel or no one else, can raise any questions about the good faith of Mr. Russo's recorded projections regarding Niaspan, and given that Mr. Audibert's for Niacor are very close, it is very difficult for complaint counsel to challenge the good faith of Mr. Audibert's projections for Niacor. Indeed, I don't think they have. When I read their brief, there was at least one place where they actually relied upon Mr. Audibert's projections for Niacor.

Next, Schering made a very substantial offer to -- pardon me, Your Honor. Schering made a very

substantial offer to Kos for Niaspan. This is SPX 619. It's a May 15, 1997 document. You can see up at the -- up there Key -- there are two columns, Key and Kos. Key is Schering, and it shows that Schering was committing to spending $30 million a year in promotional expenses as part of a co-promotion arrangement with Kos on Niaspan.

Now, complaint counsel's argument and Professor Bresnahan's argument is that because Schering did not offer to make an up-front payment to Kos, therefore, they could not possibly, when they made an up-front offer to Upsher, they couldn't possibly have been making that for Niacor. Well, as the Court I believe has heard already, they're comparing apples and oranges.

The Upsher negotiations were for a license, an outright license to the right to Niacor-SR, where Schering was going to retain all of the sales dollars except for royalties, small royalties, 10 to 15 percent. In the Niaspan situation, it was a co-promotion they were talking about where they were going to split the monies either 50/50 or, as it turned out, on terms even less favorable to Schering than that, and all Schering's decision not to offer an up-front to Kos shows is that they would much prefer to

get all of the money from the sales of a product rather than half, and I -- may I approach the easel, Your Honor?

JUDGE CHAPPELL: Yes, you may.

MR. NIELDS: The Court will undoubtedly recall that demonstrative. It was originally created by complaint counsel, but they left off a line at the bottom which told you how much money Schering was expecting to get from each of those transactions, and under Niacor is the net present value that they projected for the rights to Niacor overseas, the license rights, and it's $225 to $265 million, and then it shows under Niaspan the net present value of Schering's hoped-for share of the sales of Niaspan, and it's $127 million.

Now, the sales of the two products were projected to be about equal, but Schering's share of the profits from those sales was way smaller on Niaspan. And then on top of that, Your Honor, this was going to be a partnership, and Kos was insisting on Schering committing to an enormous number of details, $30 million worth as I've just shown. There was a big argument about who was going to get the book sales, there was a problem about who was going to get control over the product, and there turned out in the end to be

some tensions in the relationship, because when Kos received Schering's written offer, instead of being pleased with it, they said the following.

One, we want you to take less than 50/50 -- 50 percent of the profits. If you want to book sales, we want you to pay us cash for that on top of everything else. They still wanted a huge commitment to detail, an enormous sales force, their product, and they wanted an up-front payment, and they told Schering they were insulted by Schering's offer, and Schering concluded that this wasn't a good, promising partnership to continue pursuing, and so they stopped pursuing it. That doesn't tell you anything about how much Schering would be willing to pay for all of the rights to another sustained release niacin product overseas such as they were offered by Upsher.

Next, Your Honor, Professor Bresnahan, as his next argument, why Schering must be paying for delay, he calls this the market test, and he pointed out that Upsher had sent out letters to a lot of pharmaceutical companies and asked them if they had any interest in bidding on the overseas rights to Niacor. Now, it turned out several did have an interest. In fact, there were I think four or five face-to-face meetings that I'm sure Mr. Curran will tell you about, but the

point of this is the following, Your Honor.

Professor Bresnahan had no experience with any other effort to out-license a pharmaceutical product. He didn't know what was normal, and what he was doing, in effect, would be like someone saying, I put my house on the market. In the first two months 15 people come and look at my house, nobody makes a bid, and the 16th person comes and bids $500,000. Now, if you follow Professor Bresnahan's reasoning, we would have to assume that the person who was offering $500,000 must have an ulterior motive, because nobody else offered anything.

And in fact, Your Honor, the testimony in this case, the evidence in this case is that when Schering makes a bid to license a product, it almost never knows what other people are bidding, and in some cases knows that no one else is bidding anything at all. The way they determine -- the way Schering determines what to bid for a licensing opportunity is they do their own internal assessment, just the way Mr. Audibert did, and then they figure out how much it's worth to Schering, and then they negotiate for the best deal they can get.

Your Honor, I think that brings me to what I regard as the main point and main issue here, and that is what is the evidence on the question of what was

Niacor worth, what was it worth to Schering, what did Schering in good faith believe it was worth. On this issue, complaint counsel relied on the testimony of Dr. Levy. Dr. Levy's testimony was that Niacor was not worth anything near $60 million and that that was so obvious that Schering could not possibly have been actually paying for Niacor.

Now, Your Honor, Dr. Levy testified with a great air of authority and confidence when he was in this courtroom on direct. He would stand up frequently and lecture like a professor. But it turned out frequently he didn't really know what he was talking about. Part of this stemmed from the fact that his expertise and credentials were wanting. He had little or no experience with cholesterol-reducing drugs and little or no experience licensing products overseas, and his lack of experience led him to make some egregious mistakes.

The most important one probably, Your Honor, is he used the wrong yardstick when he was looking at the issue of elevated liver enzymes from the Niacor clinical trials. He thought the right measure was 1.5 times upper limit of normal when it's actually 3 times upper limit of normal, and he just completely got the wrong result, and as a result, he wrote most of his

original report, as I think the testimony shows, related to that issue, and then he hardly mentioned it again in his actual testimony.

Indeed, it led him to say in his report that he thought that Schering should have gone out and tracked down all the people who had participated in the Upsher-Smith Niacor clinical trials, find them, redose them and actually take a plug of their liver out.

The real testimony, Your Honor, that matters I would submit is the testimony of Mr. Audibert and the testimony of Mr. Lauda, and I would like to turn to that, if I may.

Unlike Dr. Levy, Your Honor, Mr. Audibert, who did the basic evaluation of the Niacor license opportunity, had extraordinarily good credentials for that particular job. He combined in his over 20 years of experience in the pharmaceutical industry both science and marketing. He had been in the research and development department of Key Pharmaceuticals before he joined Schering. He's in the research and development department of Schering today.

At that time, he was in global marketing and had extensive experience in marketing pharmaceutical products in overseas markets. He had extensive personal experience with sustained release products,

products in which a company, namely Key, had taken a known chemical, put it in a sustained release formulation, and turned a very insignificant drug into a product that sold well over $100 million a year. He did that for -- that happened with K-Dur when he was at Key, potassium, whatever sustained release, and it became, as Your Honor is aware, a $200 million a year product. It happened with Nitro-Dur, which is nitroglycerin, put it in a sustained release patch, that became a $200 million product. It happened with Theo-Dur, which is theophylline, an old asthma drug, and that was put in a sustained release formulation. He had a lot of experience with that.

He had extensive experience with cholesterol-reducing drugs. This was as a result of the fact that he had primary responsibility in global marketing for Schering's pipeline drug ezetimibe, and he had been working on it virtually half of his time for many, many, many months. He had learned the cholesterol-reducing marketplace as thoroughly as anybody could possibly have learned it. He had talked to doctors all around the country, all around the world. He had put together symposia in the United States, symposia in Europe, to discuss cholesterol-reducing drugs, what was on the market,

what was coming on the market, what the advantages of the drugs on the market were, what the unmet needs were.

He had learned about niacin in particular. He had learned it through his work on ezetimibe, but then he learned more about it in connection with the discussions with Kos on Niaspan. So, he was unusually well situated to address the issue that Schering asked him to address in June of 1997.

He received, Your Honor, some extensive materials from Upsher-Smith setting forth the results of their clinical trials. It is SPX 3, and I guarantee, Your Honor, if we haven't already done so, we will make a copy of this -- will send a copy of this document to the Court. It's an important document. It has a significant amount of detail in it, way more detail than Schering ever had from Kos about Niaspan.

Mr. Audibert described the process that he went through in order to evaluate this drug. He said it was the same that he always does. The first question he asked himself is, do I know the marketplace? Do I know the market for this type of drug? And the answer was, yes, he knew it already. He knew it extensively. He had been studying it for months.

The second question he asked himself is, is

there a -- what he called a proof of principle? In other words, does this drug work to treat the condition that it's supposed to treat? The answer, again, was yes, and he already knew it, because niacin was a very well-known cholesterol remedy. It does all the right things. It reduces bad cholesterol, it raises good cholesterol, reduces triglycerides and reduces what's called Lp(a).

He knew that there had been long-term studies on niacin that established that it had long-term good effects in slowing down atherosclerosis and in preventing the recurrence of heart attacks, and he knew that these studies had been sponsored by NIH, and he knew that niacin was recommended by the NCEP for treatment of cholesterol.

The third -- and by the way, Your Honor, I'll get to due diligence in a little bit, but in a normal case, an enormous amount of due diligence would be done on a new chemical entity to answer those two questions, what's the marketplace like and does this drug work, is there a proof of principle.

So, the next question he asked is, is there an unmet need? And the answer was yes, because there were two problems with previous niacin products. For immediate release niacin products, they caused

flushing, which wasn't dangerous but it prevented people from taking the drug. And for sustained release, there had been some sustained release niacin products that had caused elevated liver enzymes, and one of them was something like 66 percent of the patients that took it, and that was unacceptable. So, there was an unmet need. If a niacin product could be developed that solved those two problems, it would fill an unmet need.

And lastly, he turned to the question of whether Upsher's product did solve those two problems, and he looked at the clinical trials, and it was very clear that they did. They demonstrated efficacy. They demonstrated that the amount of flushing had been cut to a quarter, what it was for immediate release niacin products, and the incidence of liver enzyme elevations had been cut from 66 percent to 4 percent, and it was now right in the range of the statins that were market leaders in cholesterol reducing.

He also ascertained that for those few people that did get liver enzyme elevations, that when they stopped taking the drug, the liver enzymes returned to normal. That's very important, because the way -- that's -- the way doctors deal with statins that also have liver enzyme elevation issues is they monitor, and

for the few small percentage of patients that actually have elevated liver enzymes, they simply take them off the drug.

Then he turned, Your Honor, to his sales projections. First he looked at the market size, and the cholesterol-reducing market is huge, $4 billion overseas when he did it and growing rapidly, and then he addressed the question of share, and he projected a very modest share for Niacor. He decided to position it as a low-priced drug overseas for a lot of reasons that we've set forth in our brief, and he also decided that it would be positioned for use in combination with statins.

He made a number of other assumptions. They are all set forth in his report and in his testimony. He has explained the bases for all of those assumptions in detail there in his testimony also, and he came up, Your Honor, with the sales projections that -- nope, wrong ones -- that we've shown you previously. As the Court knows, these are very similar to the ones that Mr. Russo came up with for Niaspan. They result in a net present value of $225 million to $265 million when you take into account the royalties that Schering was going to owe Upsher.

Your Honor, Mr. Audibert testified that these

sales projections represented his best business judgment at the time. Nothing has been introduced into evidence to impeach that testimony, nothing in cross examination, nothing in argument, and those sales projections clearly produce a net present value profit stream to Schering that makes the rights to Niacor worth way more than $60 million.

Now, complaint counsel says that, well, just because you've got a product with a net present value in terms of its income stream of $225 million, that doesn't mean that you shell out $225 million for that product, and complaint counsel is right. You don't. If Schering sees a product that's worth $225 million in terms of its income stream, they are not going to pay $225 million for it. They will only enter into a transaction they think will be profitable.

There's a concept called internal rate of return, and any corporation, including Schering, that invests money in a new product is going to want a handsome internal rate of return before they're willing to do the deal. Dr. Horovitz testified about that, Your Honor, in some detail, and I'd like to put it on the screen.

"QUESTION: Dr. Horovitz, could you explain now what internal rate of return is?

"ANSWER: Yes, that's the percent return on their money for the investment. Here, with each of these projected possible payments, which represented most of the money Schering would expend to get this drug on the market, you want to know what the return is on them making that investment. They can take their $100 million, let's say it's $100 million, and invest it in secure treasuries or something like that and get a certain return. In this case, we determined that if this project went the way it was planned, they could get a return of 35 percent on that $100 million, and most of the pharmaceutical companies I'm familiar with, they would be very happy with that return."

So, yeah, it's true, you don't pay $225 million to get $225 million, but the evidence in this record is strong and uncontradicted that you would pay up to $100 million, and you would certainly pay $60 million, which is what Schering paid.

Now, Dr. Levy testified and complaint counsel has argued today that $60 million was unprecedented, just a huge amount of money, inconceivable that Schering would pay that much up front, noncontingent, for anything and certainly not Niacor. Now, there are a couple of things wrong with that, but I'm not going to have to spend much time, I don't think, because I'm

going to show Your Honor something in a moment.

The first thing, of course, is that complaint counsel is completely ignoring the fact that in most deals that Schering does and in most deals that other pharmaceutical companies do, they calculate the total investment that the project will require, and they commit themselves to various kinds of essentially noncontingent investments, either in research and development, stock purchases, promises to pay simply when their partner has done another study, and up-front payments, and when you look at deals that way, the Upsher deal is not at all at one end of the spectrum. It's in the middle.

But I'd like to show Your Honor some facts about a particular deal that was done very close in time, and it is the most analogous deal that we can find. Oh, Your Honor, here we go again. This is in camera.

JUDGE CHAPPELL: Okay. By the way, what's a good time for a break?

MR. NIELDS: What would be a good time for a break --

JUDGE CHAPPELL: When do you plan to move into your AHP/ESI phase?

MR. NIELDS: In about 10 to 15 minutes I would

say.

JUDGE CHAPPELL: Okay, I'm going to have to ask the public to leave the courtroom. We are going to be considering an in camera document. You'll be notified when you're able to come back into the courtroom.

(The in camera argument continued in Volume 38, Part 2, Pages 8782 through 8784, then resumed as follows.)

JUDGE CHAPPELL: It looks like we lost a lot of our public.

You may proceed.

MR. NIELDS: Your Honor, due diligence, I'd like to address due diligence, if I may. Complaint counsel criticizes the amount of due diligence that Mr. Audibert and Mr. Lauda did. Both of them testified -- Mr. Audibert was very specific, and I'm going to say this in response to one of the things Ms. Bokat said. Yes, he absolutely, under ordinary circumstances, when he's doing a -- one of these commercial assessments, he communicates with people in R&D and sometimes regulatory when there are issues that he doesn't understand and he needs further scientific expertise, and he testified he didn't do that here because there were no such issues, and one certainly would have to wonder if there's anyone at Schering-Plough that had

any more knowledge and expertise about cholesterol-reducing drugs in general and niacin in particular than Mr. Audibert.

Both Mr. Audibert and Mr. Lauda testified that in their business judgment, they had done the diligence that was due on this project. In effect, they both testified that in their business judgment, they were not likely to learn anything more by doing additional diligence that would affect their judgment. That's their testimony, and that testimony has not been impeached, and it isn't for lack of trying. Complaint counsel tried as hard as they possibly could to find something that if they looked further they would have found and it would have made a difference, and they came up with nothing.

All they did was over and over and over and over again, they came up with a document that said Upsher had another pharmacokinetic study to do and Schering didn't know that, but their own expert Dr. Levy said that doing a pharmacokinetic study is as easy as falling off a log, and Mr. Lauda testified expressly that knowing that they had this one other small, three-week study left to do would have made absolutely no difference whatsoever to his evaluation of that product.

So, they made a judgment at the time that they were not likely to find out anything that mattered by doing more diligence, and there is nothing that suggests there was anything wrong or incorrect about that judgment.

The real issue in a way, Your Honor, or the real problem I should say, it's not the real issue, is that Schering and Upsher both made a decision later on not to market this product. I mean, if this product had been marketed, we wouldn't be here, and complaint counsel is attributing the decision not to market that product as an indication that they never had any intention to market it in the first place, but that's not what the evidence shows at all.

What the evidence shows, and there's testimony about this and external corroboration, very powerful corroboration, that what happened was that Niaspan hit the market first and did way worse than anyone, including Schering, anticipated, and once they learned that, their faith in this product disappeared, and they decided not to invest anything more in it.

This, Your Honor, just happens to be a stock chart, and I'll show you some sales data in a minute, but this kind of graphically depicts what was going on. When the stock price of -- when Schering did the deal

and paid $60 million for Niacor, the public was valuing another sustained release niacin product at about $500 million. You have to discount a little, because complaint counsel is right that Kos had some other products that they were working on, but basically their value depended upon Niaspan.

In fact, the public had paid $60 million for a 29 percent interest in the company in April, but by the time June rolled around and Schering is paying the money, the public is valuing sustained release niacin products way more than that.

Then, just about the time Schering was supposed to get the data package on Niacor so they could start preparing overseas filings to get the drug registered, Niaspan launched its product, and the results of the sales became public, and you see the stock price drop precipitously, and when Schering made the final decision not to go forward with the product in October of '98, you'll see the price had dropped to almost a tenth of its former level, and that is referenced in Mr. Audibert's memorandum in which he is explaining why Schering isn't going forward.

These stock prices are based on these sales numbers, Your Honor. The top line is Mr. Russo's projections, which were conservative compared to the

market analysts, and you'll see that the actual sales were about a third of what he projected, and if you look at what the market analysts were projecting, it is an even smaller fraction, the actual sales were an even smaller fraction, and as Mr. Lauda testified, first of all, that told Schering something about how doctors were actually going to respond to this drug, and it also meant that they weren't going to get any bounce overseas from registration and sales in the United States of Niaspan.

Indeed, overseas people were likely to be very discouraged by the fact that the other sustained release niacin product had bombed in the U.S. So, they abandoned the product. This is not unusual.

If you recall, Dr. Levy testified about I think nine different licensing deals that Schering did, and then Mr. Lauda came in and testified about them and said that six of them had simply not worked at all. Three of them had been very successful, but six of them had not, and that's a normal batting average in the pharmaceutical industry.

Your Honor, the conclusion, I would submit, is as follows, at least the conclusion that we believe matters to this case, the Upsher-Smith case. We believe that the evidence demonstrates that Mr.

Audibert is credible. We believe the evidence demonstrates that his sales projections represented his best business judgment at the time. We believe that those sales projections, the evidence shows, support a net present value in profits from Niacor of $225 million to $265 million.

We believe that that supports a finding that $60 million was a fair price for Niacor, particularly given the 10 to 15 percent royalty rate that Schering was agreeing to. We believe that that supports a finding that the $60 million was, in fact, paid for Niacor, not for delay. We believe that supports a finding that the $60 million was not a disguise and that that supports a finding that complaint counsel have failed to meet their burden of proof which they undertook to establish that the Upsher-Schering agreement was unlawful.

That finishes my remarks on Upsher, and this would be a good time for a break.

JUDGE CHAPPELL: Okay, Mr. Nields, let's take a short recess. We will reconvene at 4:30.

(A brief recess was taken.)

JUDGE CHAPPELL: You may proceed, Mr. Nields.

MR. NIELDS: Thank you, Your Honor.

I am going to turn to ESI, although some of the

things I'll be saying from now on are going to apply to both cases as well.

JUDGE CHAPPELL: I wasn't trying to restrict you. I was looking for a transition point.

MR. NIELDS: I see.

My first point, Your Honor, on ESI is that Schering believes that these cases ought to be analyzed under the rule of reason. We are not sure exactly what antitrust cases complaint counsel are reading, but we think that matters, because the antitrust cases we've been reading say that in a rule of reason case, the Government must prove with evidence that the conduct alleged had the effect of harming competition.

Your Honor, we believe this is a rule of reason case because, first of all, the leading treatise on antitrust law says it is. It says very clearly that settlements of intellectual property disputes are to be analyzed under the rule of reason, even if the settlement would be per se illegal if done outside of the context of settlement of an intellectual property dispute. That's in our brief or maybe I should say briefs, it's been in several of our briefs. Complaint counsel has essentially not responded to that authority at all yet.

The Commission, Your Honor, has already said

that these kinds of cases need to be analyzed individually with regard to their particular facts, and the Commission has proceeded especially carefully in the case of settlements, and indeed, at least one Commissioner has written so far that he believes that a per se rule applying to so-called reverse payments in connection with a settlement would be inappropriate and that these are rule of reason cases.

Additionally, they are, Your Honor, settlements, and there is a very strong public policy in favor of settlements. Courts spend enormous amounts of their time and effort trying to get cases settled, because if they couldn't, they wouldn't be able to manage their dockets. There are very strong public policy reasons favoring settlements.

The Cardizem case, Your Honor, and the Terazosin case, if I'm pronouncing those correctly, are not partial settlements as complaint counsel has indicated. They're just not settlements. And the courts that applied per se rules in those cases were at pains to emphasize, these are not settlements. The agreement was a flat-out payment of money in return for staying off the market, no settlement, no compromise, no nothing, and the courts emphasized that fact in those cases.

The case law that speaks to the issue of when you have a per se rule and when you have a rule of reason rule all say that you don't have a per se rule unless the effect of the conduct in question is obvious, and I would submit, Your Honor, that whatever else you can say about these agreements, the effect is not obvious, at least no anti-competitive effect is obvious.

I've got my familiar -- this happens to be the Upsher-Smith settlement time line on the board. It's uncontested that the settlement permits Upsher-Smith to enter five years before the patent expired as a settlement of a case in which Schering had a claim that Upsher had no right to be on the market at all. Now, you simply cannot say that that settlement, letting them in five years early, was obviously anti-competitive. It's not obvious. It may have been and it may not have been.

The other thing, Your Honor, that the case law says, Supreme Court case law, is that the courts don't develop a per se rule until they have had sufficient experience in the particular issue involved, the particular business practice involved, to gain confidence that they know whether or not it is a kind of conduct that will always or almost always result in

an anti-competitive act.

As I said before, if this is a rule of reason case, then complaint counsel must prove that in this case, this settlement led to an anti-competitive outcome, that it was bad for consumers.

Now, Your Honor, I would submit to you that if we're correct that these cases are rule of reason cases, it is hard to imagine a less appealing case being brought by complaint counsel than the one challenging the Schering-ESI settlement.

First of all, complaint counsel has hardly proved anything other than there was a settlement that had a payment in it. If that's not per se, they've got to prove something more, and they have proved nothing. They didn't even call a witness to testify about that case. I believe the only testimony in this trial was 15 minutes of direct testimony from Professor Bresnahan about the ESI settlement. That's it, and that's not even mentioning the fact, Your Honor, that in terms of this being unappealing, that this settlement was one that was engineered under court supervision.

Courts around this country have mediation projects, and frequently, as in this case, the mediator was a magistrate judge. This has got to be one of the least appealing antitrust cases ever brought under the

rule of reason.

Now, they promised proof, Your Honor, at -- when we were here last summer and we were arguing our motion to dismiss, they promised that they would submit proof that there was payment for delay. That's what they promised. They said that's our burden. Your Honor asked them. They said that's our burden, we're going to prove it, and at that argument they told you the two ways that they had in mind of proving it.

They said either we're going to prove that there was another settlement that the parties would have entered into with an earlier entry date if they were forbidden from using money, that was way number one. Well, they haven't put in any proof like that at all in this case. Indeed, the proof they introduced in their direct case, you didn't see this because it was in deposition form or investigational hearing form, the proof they put in was to the contrary. Indeed, they put in testimony by AHP/ESI witnesses who said, and this confirms what the Schering witnesses said, that Schering took the -- first of all, Schering wouldn't offer any settlement for about 14 months of court-supervised mediation, and finally, Schering said, we will settle by permitting you to come in on January 1, 2004, and AHP said it was very clear to them that

Schering wouldn't let them in a day earlier under any circumstances, that they would go to trial. So, their own proof shows there was no other settlement available or that could have happened with an earlier entry date.

Their second way they said they could prove payment for delay was to prove that the payment had resulted in a settlement with an entry date later than the expected entry date under litigation. That's what they said. Well, they haven't proved that either. Their only attempt to prove it came through the testimony of Professor Bresnahan, who again they have not mentioned. They haven't mentioned his testimony today. He said, for example, "If an entrant would only find it worthwhile to settle if paid something, then we can be certain that the settlement contract delivers less competition than would litigating."

Now, that's virtually a per se rule, but never mind that for the moment, that's the way they were going to prove that the settlement called for a later entry date than you would expect from litigation. The opinion of Professor Bresnahan, that if there's a payment, it's always going to produce an entry date later than what's expected under litigation.

The problem with that testimony is that all the other economists in this case and outside disagree with

Professor Bresnahan, and now complaint counsel has admitted that he wasn't correct. Here's what complaint counsel says in their brief post-trial, and they're referring to the testimony of Schering's experts that Professor Bresnahan's wrong and that settlements with payments don't always lead to anti-competitive results. They say, "Respondents' economic experts offer various theoretical models that purport to show situations in which a reverse payment could end up in a settlement that is not anti-competitive..." Then they say, "These models do lay out limited conditions in which there are settlements that parties prefer to litigation and provide more competition than is expected under litigation..."

Then they say this, Your Honor, which is even more surprising, they say, "Schering incorrectly suggests that Professor Bresnahan's analysis was based on the view that the mere presence of a 'reverse' payment in a settlement would establish that the settlement was anti-competitive." So, apparently they even deny that Professor Bresnahan says that the mere presence of a reverse payment shows an anti-competitive outcome. Right there, they're telling the Court they need more than just a mere payment, but they didn't prove more. They just didn't.

In fact, Your Honor, such additional evidence as there is in the record hurts them, because in Schering's case, in Schering's case, Your Honor, we introduced the testimony of Charles Miller, a patent litigator expert, who reviewed the records in the ESI case, reviewed the evidence that would have been offered at trial by both parties, reviewed the arguments that both parties had made and were making, and reached the opinion that Schering had a very strong case and that the settlement date -- may I approach?

JUDGE CHAPPELL: Yes.

MR. NIELDS: -- that the entry date under the settlement, January 2004, fairly reflected the likelihood that Schering would win the litigation.

Complaint counsel then hired their patent litigator expert, Mr. Adelman, and had him review the record of the ESI litigation and the Upsher litigation. Now, this is a guy who can testify. He's testified 150 times as an expert witness in patent litigation, and he testified here about the Upsher case, but he never said a word about the ESI case. He never got his bat off of his shoulder. He did not attempt to refute the opinion of Mr. Miller on the ESI case. He did on the Upsher case, not on the ESI case.

So, such evidence as there is in the record on

the question of whether this settlement was at an entry date earlier than one or later than one would expect under litigation, such evidence as there is refutes complaint counsel's claim. More tellingly, complaint counsel simply never offered any evidence, either opinion, theoretical, practical, empirical, anything else, that this entry date was unfair to consumers, that this entry date produced less competition than a non-settlement would, than continued litigation.

As a consequence, Your Honor, if this is a rule of reason case, and we believe it is, they have not met their burden.

Now, complaint counsel in their statement here today, I just want to pick up a few loose ends here on this case, said that -- and I'm pretty sure I got this right, as I went back on this screen here and scrolled backwards to read what it said, but maybe I misinterpreted it somehow, but I believe that complaint counsel said that when Mr. Driscoll agreed to settle the case on that Friday night when he was at the Nets game and he was talking to Judge Reuter on the phone, that this agreement had nothing to do with Schering licensing products from AHP.

Well, that's not true, because the agreement that was inked in Judge Reuter's chambers in his

presence, and as the testimony went, while he was looking over the shoulder of the guy that was writing it, makes express reference to AHP licensing buspirone and enalapril to Schering.

I think I've got the whole part. It's hard to read, Your Honor, and I have highlighted it, and it says as item 4, "ESI grants exclusive marketing rights to ESI's generic version of buspirone and enalapril in Europe for 10 years from signing to Key," and then there's another provision of the agreement that also relates to that.

Now, the testimony was that -- and by the way, I should also say that it is true that Judge Reuter never saw the final agreement, the extended agreement that was signed in June of 1998, but Judge Reuter did see this document, and the testimony is he had a lot to do with this document, and he -- and the testimony is he knew all of the financial terms in this document, and what I'm telling the Court now is that all of the financial terms that complaint counsel objects to are in this handwritten document, a total of $30 million, $15 for the license to enalapril and buspirone and 15 in the form of $5 million plus the $10 million debt, it's all in this document.

Everything that they say is a violation of the

antitrust laws is here, except for the one provision that talks about what other potassium chloride products AHP is not permitted to market until 2004. The basic parts of the agreement they object to are in this document which was inked in Judge Reuter's presence and under his urgings.

And Your Honor, I would say this. It is absolutely true -- and this differentiates the two cases -- that in the ESI settlement, $15 million was for the license rights to buspirone and enalapril, and complaint counsel is not really objecting to those, but $15 million, tentative, contingent, is not for licenses, not for licenses.

Now, my point is this. Complaint counsel has pictured Schering repeatedly, and they say this as though they have proved it, they just say it, just rolls off their tongue, they say Schering is a company that just disguises things. They hide their payments in licenses. They've said that over and over again. They just wanted to make it look good, so they put the $60 million into a license agreement.

Well, if we were that kind of company, why is it that we didn't put all $30 million into a license agreement? Well, the answer is very clear and it's in the testimony. The licenses weren't worth $30 million.

They were worth 15 and no more, and Schering wasn't going to pay a dime more for the license than what it was worth. We didn't like paying $15 million on top of that that wasn't for a license, but we weren't going to call it a license, and we weren't forced to do it by the judge either, Your Honor, and we've never said we were forced to do it by the judge.

We were influenced to do it by the judge, you bet your life. We told him that we had antitrust concerns about it, but we couldn't tell him it was per se illegal, because it's not. And so when the judge urged us and urged us and urged us that Friday night, Schering agreed. We weren't forced. We were certainly influenced, and I don't know a lawyer in the country or a company in the country that doesn't respond to the authority of a federal judicial officer. This is a very unappealing case that complaint counsel has brought against Schering based on this agreement.

Your Honor, I have one other topic that I would like to address, and that's the issue familiar to the Court of monopoly power.

First of all, I would like to just make clear that complaint counsel continues -- continues -- with the position that they must establish monopoly power in order to establish the unlawfulness of either of these

agreements. They call it the monopoly screen, and they agree that if they don't get through the monopoly screen, that's the end of their case. And they reiterate this in their response to our finding number 3.5 -- I hope I got that right -- and that's recent. There was some indication that they might be walking away from that, but they didn't.

The second thought, Your Honor, is that I believe it's common ground that the fact that Schering had a patent is not enough to establish monopoly power, and that comes straight out of the Intellectual Property Guidelines, which says, "The agencies will not presume that a patent, copyright or trade secret necessarily confers market power on its own."

They tried, Your Honor, in the trial of this case to establish market power in the traditional way, which is to prove what the market is and then prove what Schering's share of that market is, and hopefully they would prove we had a monopoly share, but they misdefined the market when they did that, and they misdefined it because they excluded all of the products that K-Dur competes with, and there are many of them. There are potassium supplements, potassium chloride supplements. Many of them are pills of one form or another. K-Dur is a pill. They are clearly

substitutable one for another.

The testimony is uncontradicted that they are therapeutically equivalent, and the only difference is with a K-Dur tablet you take one big tablet, and if you take some of the competing pills, you take two pills, you can take them in swallow two pills. Then when you include all those products in the market, Schering ends up with a market share of less than 40 percent, and the case law is very clear that under 50 percent, you don't have monopoly power.

So, complaint counsel has gone to a fall-back position, and their fall-back position is that they've shown monopoly power because K-Dur's prices are higher than the generic prices. Now, the first thing wrong with that, for starters, is that, as the Seventh Circuit said, "A finder of fact cannot infer monopoly power just from higher prices." If I knew how to work this machine better, Your Honor, I would know how to call this thing up quickly. There, that gives you the citation.

The next problem, Your Honor, is that we probably should take a look at what the prices actually were. Here are the prices of some of the competing products on the market, and what it shows you is that at various times, really at all times, K-Dur is priced

equal to or under other brand name potassium chlorides but higher than generics.

Well, that doesn't prove anything other than that generics have lower cost structures than brand names, because generics spend almost no money promoting their products and very little inventing their products. Mostly they copy the brand name product. The brand name companies spend very substantial amounts of money promoting their product and investing in their brand, and they spend even more money inventing, developing, R&D.

And Your Honor, the law is pretty clear that the fact that a company has higher prices because it is a brand name company doesn't remotely indicate that it has monopoly power. And I've put something up from a book written by Richard Posner, and this is the person who is now I guess Chief Judge of the Seventh Circuit Court of Appeals and who Professor Bresnahan touted during his rebuttal testimony, and he wrote as follows:

"So far as appears, the difference in price between national-brand and house-brand bleach is fully explained by the higher cost of advertising incurred by the manufacturer when he sells under his own brand name, and if so the price difference need not connote monopoly power."

And Your Honor, at page 70 of our initial brief, we have a very long quote and very interesting one from Hovenkamp in his antitrust treatise that makes the same point but even more strongly with respect to a company that invests in R&D. Indeed, he begins his quote by saying, "Market power is a firm's ability to profit by raising price above the competitive level, with the competitive level generally defined as marginal cost. But such a criterion for measuring power is very hard to make workable in the case of intellectual property." That's because intellectual property, you invest an enormous amount in development up front, and the economists don't count that toward marginal cost.

So, the bottom line, Your Honor, is that under neither of the ways that complaint counsel has attempted to do so have they established monopoly power, and we would submit, therefore, first of all -- we would submit that -- we would request that the Court rule in our favor on the following grounds, at least.

One, they failed to prove monopoly power. Two, in neither case, Upsher nor AHP, did they establish that these settlements were worse for competition than litigating would have been. And in the case of Upsher, Your Honor -- and this is the simplest one -- we would

ask that you rule in our favor because they failed to prove that the Niacor license deal was anything other than a fair value deal.

Thank you very much for listening, and I apologize for taking so long.

JUDGE CHAPPELL: Thank you.

Upsher?

MR. CURRAN: Your Honor, if I understood Mr. Nields correctly, he at one point was suggesting that generic companies are freeriders at times. Sometimes their lawyers are as well, and I'm going to use one of his charts, if I may, Your Honor.

This chart that Mr. Nields had up a few moments ago obviously depicts the Schering settlement with Upsher-Smith. It indicates June of '97 when the settlement negotiations were taking place. It indicates September of '06 when Schering's patent expires. And naturally, toward the middle section, it talks -- it identifies September 2001 as the date upon which Upsher was entitled to enter with its generic product under the settlement agreement that was reached.

What I'd like to do for a moment, Your Honor, is put ourselves in the shoes of Mr. Ian Troup of Upsher-Smith in June of '97. He had a product he

wanted to bring to market, but he was subject to patent litigation that prevented him from doing so. If he persisted in defending the patent suit, he might win or he might lose. If he were to lose, he couldn't come on the market until September of '06. If he were to win, well, obviously that's a good outcome, but back in June of '97, not only did he not know whether or not he would win, he didn't know when he would win if that were to be the outcome.

Now, in the trial of this matter, we heard expert witnesses sit in the witness stand over there, including complaint counsel's witnesses, talking about how long patent litigation takes and how many twists and turns it can have. If I recall correctly, one of their patent experts, Professor Adelman, testified that the litigation in the District Court alone could take five years. The appeal process in the Federal Circuit could take three years, and half the time it ends up in a reversal.

Dr. Kerr, one of our experts, testified in similar terms. So, there really can be no dispute but that the best possible outcome for Mr. Troup here would have been somewhere in the midsection here. The best thing that could have happened were if he were to win, you know Schering's going to appeal. Who knows what

the outcome would be? But assume Schering -- assume Upsher even wins the appeal. By the time Upsher-Smith gets on the market, we're looking in the midrange section here anyway. And by settling with the September '01 entry date, Mr. Troup guaranteed -- guaranteed -- that there would be generic entry fully five years before the patent were to expire.

Now, in this case, no expert witness, no fact witness, no witness at all sat in the stand over there and said this September '01 entry date isn't right. Mr. Troup should have negotiated to let's say June of '01 or let's say September of year 2000. No witness testified that the September '01 entry date was unreasonable.

Instead, the sole basis of complaint counsel's theory that this is an anti-competitive outcome hinges on the so-called Niacor-SR license, and I'd like to talk about that. Mr. Nields talked about Schering's evaluation of Niacor-SR. I would like to talk a little bit about the evidence indicating that Upsher-Smith also thought back in June of '97 that Niacor-SR was a very promising drug and that when it entered into the separate side deal for Niacor-SR and the other products, that it entered into that agreement in good faith with a belief that the payments Schering was

going to be making were in line with fair value for those products, and as Mr. Nields pointed out, Your Honor, of course, complaint counsel and Professor Bresnahan have acknowledged repeatedly in this courtroom and in filed papers that they have no problem with a patent settlement that has a separate side deal for fair value.

So, again, as Mr. Nields was pointing out, if we can prove that the Niacor-SR license was roughly worth what Schering paid for it, that ought to be the end of the case with respect to the Upsher-Schering settlement. In fact, I can go even one step further. Professor Bresnahan said it's a subjective inquiry, which -- and Professor Bresnahan, Your Honor, you'll recall testified that if Schering had reached a stand-alone determination that those licenses were worth what they were paying, then he would have no problem with it competitively.

Well, that's what occurred here. That's what the Audibert valuation and the Schering board of directors valuation and their net present value analysis and so forth was all about. It justified the payment terms that Schering agreed to.

Now, on the Upsher-Smith side, Your Honor, you will recall you heard a number of witnesses, flew out

here from Minneapolis and talked about what their perceptions were of Niacor-SR back in '97, and we reviewed with them documents created at or around that time, and as Ms. Bokat reminds us repeatedly, contemporaneous documents have special probative value. Well, we relied on those contemporaneous documents.

Those documents indicated, they proved, that Upsher-Smith spent $13 million developing Niacor-SR in the years leading up to 1997. It was far and away its number one R&D project. It dwarfed all of their other products combined by comparison. Most of that money was spent on major clinical studies, sites all around the country administered by doctors, well-regarded physicians in cardiology, lipidology and other areas of specialty. Hundreds of patients were put through these pivotal clinical studies. Major CROs, contract research organizations, were enlisted at considerable expense.

The shareholders of Upsher-Smith, Your Honor, sacrificed distributions for years to finance the development of Niacor-SR. You may also recall Upsher-Smith executives who testified here, Mr. Dritsas, Mr. Kralovec, Dritsas being the marketing head, Mr. Kralovec the CFO. They testified that they themselves and other executives forewent annual bonuses

so that that money could be invested into the Niacor-SR product and development program.

This was clearly the crown jewel of Upsher-Smith's development efforts, and Your Honor may recall that when Mr. Troup was here testifying, he said that it was -- excuse me, it was the promise of Niacor-SR in part that led him to come to Upsher-Smith to begin with. You may recall he was testifying about his interviewing for the position with the owner of Upsher-Smith and how the promise of Niacor-SR was one of the things that encouraged him to come to Upsher-Smith.

In August of '96, Your Honor, only ten months before the June '97 settlement, Upsher-Smith convened a blue ribbon panel of cardiologists and lipidoligists, flew them into Minnesota for a two-day session. Those experts reviewed the clinical data that had been assembled, and they encouraged Upsher-Smith to proceed with the marketing of the product.

You will recall perhaps one of the members of that blue ribbon panel, Dr. Gregory Brown, flew in here from Seattle. We subpoenaed him to encourage him to attend. You may recall he was taken a little bit out of order and was anxious to get back to Seattle. You may also recall he was -- he was the witness who --

because he's a leading national practitioner on niacin therapy and so forth, he was a little bit put off by the fact that he wasn't regarded as an expert witness, but Your Honor was kind enough to explain that that only had to do with the designation attributed by counsel.

Well, Dr. Brown corroborated the testimony of the Upsher-Smith witnesses that he and the other members of that blue ribbon panel reviewed that data and encouraged Upsher-Smith to proceed, told them that they had a good, valuable product. Dr. Brown, you may recall, not only participated on that panel, but one of the qualifications that led him to have a spot on that panel was because he had been treating patients with niacin, including extended release niacin, for years and had published some of the leading studies in the field. You may recall the acronyms the FATS study, the FATS II study and the HATS study.

Your Honor, in and around that time period leading up to June of '97, Upsher-Smith thought that Niacor-SR had great promise. Numerous of the executives testified that at that time they expected Niacor-SR to ultimately be able to achieve sales in the hundreds of millions of dollars a year. That was not just spoken words from witnesses. There are documents,

internal Upsher-Smith documents, corroborating that testimony. We've referred to these in our briefs. Of course, USX 1563 is one of them.

In that document, Your Honor, you will see a sensitivity analysis of projections depending on how much market share and at what price they'd get projecting a range of annual sales for Niacor-SR between roughly $100 million and $400 million. Those projections contemplated a substantial change in Upsher-Smith.

Your Honor may recall that Upsher-Smith in 1997 and 1996 did not have its own field force of representatives to go out and encourage doctors to prescribe their products and so forth. They had a few people at a telephone bank. They obviously did not expect to achieve the hundreds of millions of dollars in sales with that marketing effort, but as CFO Kralovec and as marketing executive vice president Dritsas testified, they contemplated developing a sales force specifically for this Niacor-SR product.

Now, Your Honor, in early 1997, in the months leading up to June of '97, there was an external development that further encouraged Upsher-Smith and corroborated their internal forecasts, and that was the developments regarding Kos Pharmaceuticals. I know

you've heard a lot about Kos Pharmaceuticals during this trial. I submit that the key relevance of Kos is that it was by all accounts principally a one-product company, Niaspan, its extended release niacin product.

Granted, it had a couple of other pipeline products, but if you look at their red herring, their prospectus, if you look at the analysts' projections and so forth, those other pipeline products had an insignificant percentage of Kos' worth. In fact, our expert economist, Dr. Kerr, meticulously went through some of the Kos' annual reports and other projections that Niaspan was to constitute about 95 percent of the expected revenues of Kos. In fact, 100 percent in the first few years. So, we have in a sense an independent market valuation of an extended release niacin product in and around the time period of the June '97 settlement.

What did that market test, if you will, indicate? Well, it indicated that the Niaspan product, the extended release niacin product, was worth hundreds of millions of dollars.

When Kos went public in March of '97, it immediately achieved a market valuation of around $200 million at a $15-per-share selling price. By the time of June of '97, the stock price had doubled to $30,

thus its market cap was about $400 million, slightly more than that at the time of this settlement.

Now, you've heard testimony, Your Honor, from folks at Upsher-Smith saying they were monitoring very closely the market developments regarding Kos. You may remember Mark Halvorsen, the head of clinical affairs, the director of clinical affairs at Upsher, testified that he maintained the Kos homepage and stock price on his desktop computer so he could monitor it on an ongoing basis.

Your Honor saw documents from Upsher-Smith's files, the actual analysts' reports regarding Kos. These are reports projecting sales of $250 million a year, giving a buy recommendation when the Kos market cap was in the hundreds of millions of dollars, and these were being circulated among Upsher-Smith executives. That's how they were assessing -- I've got one of those documents here. Your Honor may recall this analyst report. I asked questions of Paul Kralovec about this. "From Ken," yeah, that's Ian Troup's handwriting, indicating -- this was an analyst report being circulated among the top executives of Upsher-Smith, April of '97. This is USX 535, and this is one of the documents not only indicating that Niaspan was the principal product at Kos, but also

indicating projected sales of $250 million in the third full year. Those on page USL 11515.

So, as you can see, the Upsher-Smith folks had ample reason to believe they had a product with the possibility of sales in the hundreds of millions of dollars based on their own calculations and based on analyst reports and based on the market valuation of the product.

Your Honor may recall Dr. Levy was asked about these analyst reports, and he said, oh, they're all a bunch of hogwash and those people are -- he didn't say crooks, but he said something to that effect, they're all in it with the companies and they're pumping up the stock and then they dump it and so forth. Well, Your Honor, as we established through Dr. Kerr, not all of these analyst reports were from the companies that were underwriters of the stock, and we're not even suggesting that you have to credit these valuations in full. With a Kos valuation of $400 to $500 million and Schering paying $60 million for a comparable product, that's a heck of a cushion in there.

Your Honor, because Upsher-Smith had such high hopes for Niacor-SR, they wanted to maximize the return on the product. Now, as I've mentioned and as the witnesses testified, Upsher-Smith planned on developing

its own domestic sales force to market the product, but they had no such plans for Europe or the rest of the world, so in late '96, early '97, they engaged a marketing person in Europe to find a marketing partner. You heard testimony about that.

We believe that that's significant because it indicates well before June of '97, months before, in the months leading up to June of '97, that Upsher-Smith had a bona fide interest in finding a licensing partner outside of the United States for this product.

Now, complaint counsel have argued, principally through Professor Bresnahan, that the fact that Upsher didn't find a licensing partner before Schering indicates that the Schering deal was in part or in full a sham. Well, I liked Mr. Nields' house analogy, I think that's apt, but I also think complaint counsel had a witness of their own who effectively corroborated that analogy.

You may recall Mr. Egan who testified in complaint counsel's rebuttal case. He's the gentleman who worked at Searle, before that he worked at Abbott, and he had considerable experience as a licensing executive, and he said, oh, yeah, happens all the time, that companies go around marketing a product, a lot of people turn it down, it's not a good fit, they're

skeptical about the product's promise and so forth, and then you find a licensing partner, and you cut a deal. There's nothing unusual about that. That's the way it's done. So, there's no adverse inference that can be drawn from the fact that Upsher had not yet identified or had not yet signed a deal with another company before Schering.

In fact, things were just getting hot and heavy during that period leading up to June of '97. Mr. Nields mentioned five meetings. I believe Ms. Bokat might have mentioned -- might have acknowledged that there were five meetings as well. These were companies that received a nonconfidential mailing -- effectively a cold call in the mail -- from this marketing rep in Europe about a product being offered by a company called Upsher-Smith in Minnesota, do you have any interest, here's a little bit about what the product's about.

Well, five substantial pharmaceutical companies were sufficiently interested that they not only signed confidentiality agreements, but they asked for meetings with Upsher-Smith pretty quickly to review the clinical studies, and in just the three weeks before June 17th of '97, five such meetings occurred. There was the Searle meeting in Chicago on May 28th, okay, that's

about three weeks before June 17th. There were two meetings in Paris on June 3rd, Pierre Fabre and Servier, and there were two more meetings in Barcelona on June 5th, Dr. Esteve and Lacer.

Your Honor heard witnesses, including CFO Kralovec, testify that Upsher-Smith was very encouraged by the reception they were getting in the marketplace. In fact, in one of the report memoranda prepared by Vickie O'Neill who attended all five of those meetings, she reported in writing to Mr. Troup that while meeting with Pierre Fabre, Pierre Fabre representatives mentioned that, oh, a similar company, a startup company had been coming through offering something similar, and they'd been seeking $50 million up front. That was the lay of the land on the Upsher side in the period leading up to the June 17th, 1997 agreement. All factors point toward Upsher having a valuable, marketable product, annual sales, hundreds of millions of dollars, with a substantial up-front payment warranted as part of an overall lucrative package.

At the same time all these events were playing out on the Upsher-Smith side, as you've heard already today from Mr. Nields, similar things were happening on the Schering side. Schering was engaged in active negotiations with Kos, the very same company that

Upsher was using as a benchmark, as its principal competitor, its look-alike. Schering was dealing with that, was not only dealing with them, Schering was meeting with them, negotiating with them and made a substantial written proposal.

Your Honor may recall one of the -- there was a gentleman from Kos who testified here, Mr. Patel, again a complaint counsel rebuttal witness. Mr. Patel testified that he and his colleagues at Kos had been marketing, looking for co-promotion partners and then later marketing partners in Europe. Schering was the most interested company. Schering was the only one that made a substantial written proposal to Kos. So, what you have playing out in the early months, the first half of '97, you've got Schering with a demonstrable preexisting interest in a sustained release niacin product, and you've got Upsher-Smith with such a product and high hopes for it, and they came together in June of '97.

Mr. Nields talked about the projections that Schering had prepared in connection with its negotiations with Kos, okay, and obviously there's never been any suggestion that those projections are tainted in any way by some pretext or sham. As Mr. Nields pointed out, those projections are very much in

line with the projections that Mr. Audibert did a couple weeks or a couple months later on the similar Niacor-SR product. So, you had Ray Russo doing projections on Niaspan, and then you had Audibert doing projections on Niacor-SR, and understandably, for similar products, you are going to have similar projections.

As Your Honor knows, it was on the basis of Mr. Audibert's projections that the Schering board reached a net present value for Niacor-SR of $225 to $265 million. And by the way, the projections of Mr. Audibert -- and again, I'm perhaps freeriding on Mr. Nields who went before -- the projections that Mr. Audibert made were very conservative when you compare them to what the analysts were saying. So, there can't be any suggestion that he was off the reservation in the projections he did.

And of course, the evidence at trial established Mr. Audibert, who did the market evaluation, the commercial assessment of Niacor-SR, didn't even know about the patent case or that the licensing deal was a side deal for a patent settlement. So, on both sides, the Upsher side and on the Schering side, there's uncontroverted evidence of a bona fide interest in reaching the deal that was ultimately

reached.

At trial, expert witnesses came and testified before Your Honor. Mr. Nields mentioned Schering's witness Zola Horovitz. We brought Dr. Kerr, whom I've mentioned. They both corroborated the reasonableness of Audibert's projections and the amount ultimately paid by Schering in the transaction.

In fact, Dr. Kerr also analyzed and valued the additional products that were included in the license, and he came up with a range of value between $10 and $17 million.

There was ample, ample value being conveyed for what Schering was paying for. The only witness who really quarrels with that statement was Dr. Levy. Now, Mr. Nields made some comments about Dr. Levy. I don't want to pile on, but there are a couple other things that are warranted here. Dr. Levy was proffered as a valuation -- a pharmaceutical valuation expert, but he never did a valuation. He never testified that, oh, no, this package of products was worth such and such. He never did that. He just shot spitballs at what other people did.

He never did any quantitative valuation, no net present valuation on Niacor-SR, no net present valuation on any of the other products. In fact, he

didn't even recognize the names of the other products. He never even -- he never considered the production rights that were also granted to Schering under the licensing agreement.

Your Honor may recall that among the bundle of goods that Schering got in the licensing transaction, not only non-NAFTA rights to Niacor-SR and the group of other products, Prevalite, pentoxifylline and three different Klor Con products, they also got supply and production rights requiring Upsher-Smith to manufacture and provide those products almost entirely at cost upon Schering's request. Levy didn't remember, didn't know about that, didn't ring a bell, and he certainly didn't value those production rights. Astonishingly, Dr. Levy also never considered Kos and Niaspan in doing his analysis.

Even if you were to credit, for argument's sake, Dr. Levy's testimony, his conclusion was that $60 million was not for Niacor-SR. Well, that ain't what this case is about, because as Professor Bresnahan said, the $60 million staggered over three years is really worth $54 million, so he got that side of the equation wrong, and on the other side, he ignored the things other than Niacor-SR that Schering was also getting. So, even if Dr. Levy had the right answer, he

had the wrong question.

Your Honor, more generally, Dr. Levy was not an expert, was shown not to be an expert with regard to niacin products. He didn't know NCEP, which is the leading guideline issuing authority in this country. He didn't know -- as Mr. Nields said, he didn't know what liver toxicity levels were relevant. He had never heard of the people who really are experts in the field. He said he read articles, and I think he was shown not to really know what those articles were about either. He didn't recognize FATS, FATS II, HATS. His testimony, as I said, was the only testimony, the only evidence in the case that Niacor-SR and the licenses associated with it and the production rights did not justify the payment that Schering made. His testimony should not be credited.

Dr. Levy spoke about post-deal communications as well. He suggested that Upsher and Schering did not indicate a bona fide interest in going forward after they did their deal, but I think he was shown on cross examination to have fundamental misunderstandings about what occurred. He completely disregarded the developments regarding Kos, because he hadn't considered Kos' stock price either before or after June of '97.

Mr. Nields has already commented about the dramatic and precipitous drop in Kos' stock price and market capitalization in late '97. That was certainly a major factor in the companies losing their enthusiasm for Niacor-SR.

One other thing that bears mentioning, this probably only relates to the Upsher side, not the Schering side, but even before the Niaspan sales figures came out and they were disappointing in the stock market, even before that, Upsher-Smith had some concerns. You may recall, Your Honor, Mark Halvorsen testifying about this, but when Kos was given FDA approval earlier in 1997, after June -- after June of '97 but around July 28th, I believe, somewhere in that ballpark, Upsher-Smith even at that point began getting concerned, because Kos had -- was given indications, labeling indications by the FDA that Upsher-Smith had not contemplated for Niacor-SR and had not done specific clinical studies for. So, again, another thing that Dr. Levy didn't consider.

Dr. Levy also, as you may recall, during perhaps a dry, long cross examination segment by me, he was forced to acknowledge that he had not analyzed any of the extensive documentation showing what Upsher-Smith was doing on Niacor-SR after June of '97.

You may recall there were the agendas and the reports about the weekly meetings between Upsher-Smith personnel and folks at ClinTrials and the other CROs who were doing a lot of the analysis of the Niacor-SR clinical work. Dr. Levy didn't consider that stuff.

He was also shown to be just mistaken when he said that there were hardly any communications between the companies. In fact, we documented extensive communications between the companies after the transaction.

Professor Bresnahan, even beyond his basic economic testimony, he also offered some opinions relevant to Niacor-SR, but he didn't do any valuation. He acknowledged that net present valuations are important and common, but he didn't do one. He talked about this revealed preference test. I think Mr. Nields has dealt with that sufficiently already, but Professor Bresnahan had this notion that Schering rejected Niaspan, and therefore, their interest in Niacor had to be feigned. Well, that just doesn't add up when one considers that Schering, in fact, made a written substantial proposal to Kos, Kos turned it down, and then Schering later expressed interest in Niacor-SR.

The only preferences revealed by the facts that

Professor Bresnahan points to are Schering's preference to have an extended release niacin product and perhaps Upsher's preference to keep it for itself in the United States.

In fact, one other point in that regard, Your Honor. Back to Mr. Patel from Kos who testified, when he was testifying about his negotiations with Schering, he acknowledged and his notes reflect that Schering asked about worldwide rights. Schering, in those discussions, was revealing a preference for worldwide rights to a sustained release niacin product.

Professor Bresnahan also talked about this market test, I think I've spoken about that already, but his theory was that since Upsher didn't have a deal before Schering, the Schering deal couldn't be bona fide. Well, that doesn't add up, and more importantly, the real market test here is what Kos -- what the Kos Niaspan product value was on the public markets. Professor Bresnahan didn't look at that.

Professor Bresnahan talked about incentives. I think we've dealt with that, Your Honor, in our briefs, and incentives don't add up to anything here, and in fact, it's not at all clear what the incentives were. Professor Bresnahan talked about incentives I guess to violate the antitrust laws, but then that seemed to be

undermined by other countervailing incentives, and the proposed findings of fact that complaint counsel has submitted recently indicate -- they're disputing the risk aversion element of this case, and they say there Schering had no reason to be risk averse, because the people negotiating the settlement with Upsher weren't the people responsible for the K-Dur product.

Well, if they weren't responsible for the K-Dur product, why would they have an incentive to engage in an improper transaction? Anyway, it starts getting a little speculative at some point here, Your Honor.

Ms. Bokat talked today about the negotiations. As Mr. Nields said, all the negotiations prove is that the parties agreed that there would not be any payment for delay and that there would only be a side deal for fair value. There's no inference to draw from those negotiations other than that there was no payment for delay.

The Schering board presentation and the executive summary that Ms. Bokat spoke about, and it's addressed in their papers, those don't support complaint counsel's case. Quite the contrary, they corroborate the fact that this was a separate -- the licensing transaction was a separate deal for fair value, or they say a separate deal for fair value or a

separate deal standing on its own two feet or standing on its own merit.

There was also some discussion, Your Honor, about the agreement itself. As Mr. Nields mentioned, paragraph 11 of the agreement talks in terms of royalty payments, royalty payment, royalty payment. It also in the lead-in language talks about SP Licensee making the following payments. I think Ms. Bokat said SP Licensee, well that's Schering, but it's not just Schering. SP Licensee is a defined term, and guess what, it's only defined in the context of the licensing agreements, the Niacor-SR license. That's where SP Licensee is applied for the first time.

So, it appears that in the line of paragraph 11, complaint counsel is trying to elevate boilerplate to some clear indication of the parties' intent. Well, I submit, Your Honor, that the clear indication of the parties' intent as reflected in paragraph 11 is that the $60 million paid over three years were royalty payments to the Schering entity that was getting the licenses for Niacor-SR and the other products.

We've cited in our papers, Your Honor, some case law from New Jersey. This agreement, of course, is covered by New Jersey law and was drafted by a New Jersey lawyer. New Jersey law says you always look at

the surrounding circumstances and other extrinsic evidence of the parties' intent. In fact, we cite to Corbin on Contracts, and in Corbin on Contracts, where there's a discussion about the plain meaning rule and so forth, they talk specifically about New Jersey being the leader in the rejection of the plain meaning rule. California and some other states have followed suit. Virginia has not. Other states have not. In other states you have to prove ambiguity before you can look at extrinsic evidence. That's not true in New Jersey. So, any attempt to impose some rigid meaning on particular terms in this agreement that are defied by the parties' actual intentions doesn't work.

There are some other arguments advanced with regard to Niacor-SR, Your Honor, that I suspect and hope are dealt with amply in our briefs and findings of fact.

I'd like to turn to another subject, and this relates to the economic arguments advanced by complaint counsel.

Your Honor, complaint counsel and Professor Bresnahan, whom I think by no accident, his name was not mentioned during Ms. Bokat's closing, Professor Bresnahan. He was their star witness. We haven't heard much from him recently, but -- and there's a good

reason for that, because he advanced a theory that both had no basis in antitrust law and had no proof to back it up.

You'll recall he advanced a three-part test where -- again, he was the only witness for complaint counsel's entire case, Your Honor, who testified that the June 17th, 1997 agreement was anti-competitive, and his basis for that conclusion was his three-part test, and you'll recall that that test hinged on a preliminary conclusion that Schering had a monopoly, but he didn't prove that.

In fact, Professor Bresnahan's analysis, Your Honor, was patently deficient. I'm starting to sound like Dr. Levy with my adjectives, forgive me, but it clearly did not meet the standards of rigorous economic analysis as required to sustain allegations like those made in this case.

Professor Bresnahan didn't do any conventional tests for market definition. He didn't do any price studies. He didn't do any market studies. He didn't do any cross-elasticity studies. He didn't do any econometrics. He didn't do any statistical analyses of any sort.

There's been some discussion, loose discussion in the courtroom, even here today, about

supra-competitive prices and that Schering was selling at supra-competitive prices when it was selling K-Dur 20, but there was no proof of that at trial. Professor Bresnahan didn't do a comparative study on the price of K-Dur 20 versus the price of other competing products. He never analyzed costs of raw materials, manufacturing, labor, promotion.

He did acknowledge that Schering spends something like a hundred times all other companies combined on their promotion of potassium and specifically K-Dur 20, but he didn't consider how those promotional costs might affect price. He seemed to assume that K-Dur 20 was a monopoly product, but he didn't prove it. He didn't prove it through any rigorous economic analysis.

In fact, as Mr. Nields pointed out, if you are going to rely on anecdotal evidence, the anecdotal evidence suggests that Schering's K-Dur 20, in fact, was priced very comparably to other brand products. The evidence suggests that generic products were priced less, but so what? The documents and the evidence indicate that there was substantial competition among the brands and the generics.

In fact, Your Honor, there was one document that Ms. Bokat showed you, and I'm going to the exact

page, this was a document used during her closing where there was a sentence up toward the top about K-Dur 20 with a new lease on life, K-Dur 20 sales will be "re-igned" via the coordinated field force efforts of Key Specialty and Innovex. Ms. Bokat referred to that paragraph.

Right down on the same page, there is reference to generic competition continues to grow at the expense of K-Dur 20. Klor Con 10, a branded generic, has grown to 16 percent of total prescriptions. The category of generics has grown over a full point to 30 percent of total prescriptions. The growth in the generic market is due in part to the 30 percent price advantage over K-Dur 20, but managed care also plays a significant role.

And then this is critical, usage data for 10 mEq generics shows that most patients are using two tablets a day, a dose equivalent to one K-Dur 20. Your Honor, that would indicate that the majority of patients using 10 mEq generic products are doing it at the expense of the K-Dur 20. These products are competing with one another. I think the evidence established that pretty dramatically.

Your Honor will recall there was a lot of evidence at trial about therapeutic equivalence, and

some of the early witnesses in the case in particular were focused on that issue. You'll remember Mr. Teagarden and Mr. Goldberg. Mr. Teagarden is from Merck-Medco. Mr. Goldberg is from United Healthcare. They both acknowledged that there was therapeutic equivalence among K-Dur 20 and dozens of other potassium supplements.

Your Honor may recall that you specifically asked, I believe it was Mr. Goldberg, is it really therapeutically equivalent to take two 10s, sustained release, as opposed to a sustained release 20? I think it's a very good question, because one might suspect that a 10 would run out in half the time that a 20 would, but that's not the case, and he testified accurately that, in fact, taking two 10s is the exact same therapeutically as taking a 20. They both last for the same period of time and administer the same dose over that period.

Other witnesses at trial also testified about therapeutic equivalence. This is all relevant, Your Honor, because under Brownshoe, the leading Supreme Court case on market definition, the very first thing you look at when you're defining a market is the substitutability of the products, and if there was one fact that was proven beyond any possible doubt at

trial, it's that other potassium supplements are substitutable for K-Dur 20.

In fact, you may recall Mr. Teagarden from Merck-Medco testified, was forced to acknowledge, that Merck-Medco's formularies didn't even have K-Dur 20 on it for several years. Its patients survived pretty well without K-Dur 20, with all due respect to Schering.

Ms. Bokat suggested something in her closing earlier about this corrupt bargain among the parties depriving therapeutically challenged people or that it was going to have some dramatic impact on the health of people in this country because there wasn't generic competition to K-Dur 20 at some earlier point. Well, the evidence in this case indicates that any consumer who wanted a potassium supplement at a price cheaper than K-Dur 20 had dozens of alternatives at all times.

The only difference between the A-B rated generic and other potassium supplements was the benefit of the mandatory state substitution laws, because that's where generic companies get to be freeriders. That's got nothing to do with market conditions or anything else, but by government fiat, pharmacists would substitute the A-B rated generic for the brand product on account of that A-B rating. That's why

Upsher desperately wanted to get its generic product on the market. It wanted to benefit from Schering's promotional activities and brand name.

Your Honor, Ms. Bokat -- well, and Professor Bresnahan at trial often showed graphs looking something like this, and I say something like this because it may not be immediately apparent, but this graph deals with K-Dur 10, not K-Dur 20, but you see the exact same phenomenon that we see with the K-Dur 20, right? Professor Bresnahan talked with great import about, oh, this indicates when the generic came on the market, the sales of the brand name plummeted. Well, there's been no suggestion in this case that K-Dur 10 was a monopoly, okay? I don't think -- well, in Professor -- or Dr. Addanki, Schering's expert on product market, he said no one in their right minds would say K-Dur 10 was a monopoly. That's because K-Dur 10 had a 10 percent market share or something like that.

Nonetheless, K-Dur 10's sales, non-monopoly sales, show -- have the same effect upon the entry of an A-B rated generic. So, the fact that the sales volume of a brand name product falls upon A-B rated generic entry is no proof that the brand had a monopoly beforehand.

Professor Bresnahan's test was not satisfied. He was unable to show a monopoly. He was unable to show that there was a single-product product market in this case, and I submit that that failure was so dramatic, that's why we haven't heard anything about Professor Bresnahan in quite a while, because instead, there's been a shift, an audibilizing, if you will, and a shift to a more conventional rule of reason analysis by complaint counsel, an abandonment of the -- of what we've called the Bresnahan test, and instead an attempt to argue the case under a rule of reason analysis, and that doesn't work either, because a rule of reason analysis requires a number of steps, none of which have been satisfied here.

There hasn't been a showing of market power. There hasn't been a showing of anti-competitive effect. As I said at the outset, Your Honor, there's been no showing or even serious suggestion that an earlier date could have been achieved during -- in the negotiations between Mr. Troup and Schering-Plough.

Let me mention something, Your Honor, that there's no suggestion of that in this case. There's no suggestion that a date before September of 2001 was ever under discussion or agreed to and then there was a march-back of the date to September of '01. Nothing

like that in this case, no trading of money for delay, no showing that there was anything anti-competitive about the settlement that was reached.

Even if they were to satisfy that prong, Your Honor, under California Dental and other authorities we've cited in our brief, they have to deal with the pro-competitive aspects of the June 1997 agreement, and that hasn't been done here, Your Honor. There's been no consideration of demonstrable pro-competitive benefits from the agreement, such as, first and foremost, the fact that Upsher was guaranteed entry fully five years before September of '06 when otherwise it might have been excluded from the market until that point in time. So, getting Schering to abandon its effort to block entry until '06 was a demonstrable pro-competitive benefit.

Establishing a date-certain -- we heard that term during the trial, particularly from Mr. Troup -- the establishment of a date-certain of September '01 enabled Upsher-Smith to organize a significant, sizeable launch with substantial investment behind it that it was able to become a very effective competitor when it came to market.

Other pro-competitive benefits, and there was testimony about this at trial by Dr. Kerr and others,

recruitment of R&D in the products that were licensed, the inclusion of the M10. You'll recall that there's a Klor Con M10 product that Upsher-Smith sells today. If it hadn't included -- if it hadn't obtained a license for the M10 product under the June '97 agreement, there might have been more litigation dealing with that product.

The settlement also opened the door -- the settlement and the June '97 agreement in whole opened the door to other products entering the market, not just Klor Con M20, but the Qualitest product, the Warrick product. It triggered the 180-day period and opened the gates for all sorts of entry. It gave Schering excess capacity for manufacturing. It gave products to -- it gave products to Schering for exploitation in Europe where Upsher-Smith has no sales force. And of course, it saved the public resources associated with patent litigation.

Again, Your Honor, we deal with all these pro-competitive benefits with our papers. I raise them now just to point out that they were never dealt with by complaint counsel at trial or even thereafter, and they have to be dealt with, because under a rule of reason analysis, they've got to prove a net anti-competitive effect taking into consideration

pro-competitive benefits. That hasn't been done. That's the essence of the rule of reason, and it wasn't done here by Professor Bresnahan or anybody else. It was done by Drs. Addanki and Kerr, and their testimony that this was a pro-competitive transaction under the rule of reason is unrebutted.

Your Honor, the hour is late, and I was the -- I believe the third person to go when we had our opening statements. You know that was a year ago today, September 1st of -- May 1st of '01 was when we all appeared before Your Honor for the first time and gave somewhat abbreviated opening statements at that time. I've gotten used to going third in this case, and I've tried to not be repetitive and tried not to belabor any particular points. I appreciate your patience.

One thing that I do agree with Ms. Bokat about is we all should have been outside enjoying this weather today rather than debating the merits of these transactions, but I submit, Your Honor, that these transactions were pro-competitive, shouldn't have been challenged, and Your Honor should dismiss the charges against Upsher-Smith.

Thank you, Your Honor, thank you very much.

JUDGE CHAPPELL: Thank you.

Anything further?

MS. BOKAT: Your Honor, could I have a quick minute to confer with counsel and see if there's anything further?

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MS. BOKAT: Your Honor, thank you for your indulgence. We will leave the Court with the arguments we have made already today and all the pages of paper you have. Thank you very much.

JUDGE CHAPPELL: Thank you.

Hearing nothing further, we are finally, mercifully and once and for all adjourned. Thank you.

(Whereupon, at 6:00 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: MAY 1, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 5/2/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE